

EXHIBIT B9

Christian Merlo, M.D., MPH

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON &)
JOHNSON TALCUM POWDER)
PRODUCTS MARKETING)
SALES PRACTICES AND) MDL 16-2738
PRODUCT LIABILITY) (FLW)(LHG)
LITIGATION)
_____)
THIS DOCUMENT)
PERTAINS TO ALL CASES)

THURSDAY, APRIL 18, 2019

- - -

Videotaped deposition of Christian
Merlo, M.D., MPH, held at the offices of
VENABLE LLP, 750 East Pratt Street, Suite
900, Baltimore, Maryland, commencing at 9:06
a.m., on the above date, before Carrie A.
Campbell, Registered Diplomate Reporter
and Certified Realtime Reporter.

- - -

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Christian Merlo, M.D., MPH

Page 2	Page 4
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2 (Pages 2 to 5)

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Christian Merlo, M.D., MPH

Page 6

1

Merlo 6

Faculty directory printout of the epidemiology department at Johns Hopkins Bloomberg School of Public Health

65

2

3

Merlo 7

Printout of the web page from the Johns Hopkins department of epidemiology

70

4

5

Merlo 8

VeraMedica Institute invoices

83

6

7

Merlo 9

Excerpt from Expert Report Of Christian Merlo, MD, MPH; Page 46

110

8

9

Merlo 10

"Merlo Allegations of Plaintiffs Experts Methodologic Flaws"

118

10

Merlo 12

"Ovarian Cancer and Talc," Cramer, et al.

151

11

12

Merlo 13

Draft Screening Assessment Talc, Chemical Abstracts Service Registry Number 14807-96-6, Environment and Climate Change Canada, Health Canada, December 2018

165

13

14

Merlo 14

"The Environment and Disease: Association of Causation?" Sir Bradford Hill

170

15

16

Merlo 21

"Perineal Talc Use and Ovarian Cancer A Systematic Review and Meta-Analysis," Penninkilampi, et al.

418

17

18

19

Merlo 22

"Epidemiology, Concepts and Methods," Oleckno

200

20

21

Merlo 23

Chapter 14: "From Association to Causation: Deriving Inferences from Epidemiologic Studies"

206

22

23

24

Merlo 24

CDC Lesson 1: Introduction to Epidemiology

217

25

Page 8

1

Merlo 37

Excerpt From Expert Report of Christian Merlo, MD, MPH, for General Causation Daubert Hearing

344

2

3

Merlo 38

Statement from Christian Merlo Expert Report, February 25, 2019, Page 44-55

351

4

5

Merlo 39

Statement from Christian Merlo Expert Report, February 25, 2019, Page 45

353

6

7

8

Merlo 40

"Mineral Fiber Exposure and the Development of Ovarian Cancer," Rosenblatt, et al.

359

9

10

Merlo 41

"Hair Dyes, Analgesics, Tranquilizers and Perineal Talc Application as Risk Factors for Ovarian Cancer," Tzonou, et al.

374

11

12

Merlo 42

Excerpt From Expert Report of Christian Merlo, MD, MPH, for General Causation Daubert Hearing

396

13

14

15

Merlo 43

Epidemiology Concepts and Methods, William A. Oleckno

404

16

Merlo 44

"Scientists rise up against statistical significance," Amrhein

410

17

18

Merlo 46

Exhibit of a compilation of studies titled "Dose Response"

446

19

20

Merlo 47

Pro Publica Christian Merlo printout

88

21

Merlo 48

"Genital use of talc and risk of ovarian cancer: A meta-analysis," Berge, et al. (Exhibits attached to the deposition.)

378

22

23

24

25

Page 7

1

Merlo 25

"Appetite-Suppressant Drugs and The Risk of Primary Pulmonary Hypertension," Abenhaim, et al.

232

2

3

Merlo 26

NHMRC levels of evidence and grades for recommendations for developers of guidelines, December 2009

251

4

5

6

Merlo 27

Chapter 8: Case-Control Studies, Rothman, et al.

268

7

Merlo 28

"Six Persistent Research Misconceptions," Rothman

270

8

9

Merlo 29

Interpretation of Epidemiologic Studies on Talc and Ovarian Cancer by Kenneth Rothman, et al., IMERYs 209695 - IMERYs 209705

272

10

11

12

Merlo 30

Systematic Review and Meta-Analysis of the Association between Perineal Use of Talc and Risk of Ovarian Cancer, Taher, et al.

438

13

14

15

Merlo 31

"Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ)- Health Professional Version," NIH

309

16

17

Merlo 32

Modern Epidemiology, Kenneth Rothman, et al.

314

18

19

Merlo 33

Rule 26 Expert Report of Jack Siemiatycki, MSc, PhD

324

20

Merlo 34

Excerpts from Jack Siemiatycki, PhD, deposition

330

21

22

Merlo 35

Rule 26 Expert Report of Patricia G. Moorman, MSPH, PhD

331

23

Merlo 36

Excerpts from Patricia G. Moorman, MSPH, PhD, deposition on January 25, 2019

334

24

25

Page 9

1

CERTIFICATE.....

487

2

ACKNOWLEDGMENT OF DEPONENT.....

489

3

ERRATA.....

490

4

LAWYER'S NOTES.....

491

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

3 (Pages 6 to 9)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 10</p> <p>1 VIDEOGRAPHER: We are now on 2 the record. 3 My name is Daniel Holmstock. 4 I'm the videographer for Golkow 5 Litigation Services. 6 Today's date is April 18, 2019, 7 and the time on the video screen is 8 9:06 a.m. 9 This deposition is being held 10 at the law offices of Venable LLP, 750 11 East Pratt Street, Suite 900, 12 Baltimore, Maryland, for the matter of 13 In Re: Johnson & Johnson Talcum Powder 14 Products Marketing, Sales Practices 15 and Products Liability Litigation, MDL 16 Number 2738, pending before the United 17 States District Court for the Eastern 18 District of New Jersey. 19 Our deponent today is 20 Dr. Christian Merlo. 21 Counsel for the record will be 22 noted on the stenographic record for 23 appearances. 24 Our court reporter is Carrie 25 Campbell, who will now administer the</p>	<p style="text-align: right;">Page 12</p> <p>1 this year that would make it more current? 2 A. There are probably a couple of 3 articles that I need to put in there. 4 Q. Do any of them deal with 5 ovarian cancer? 6 A. They do not. 7 Q. Do any of them deal with talc? 8 A. They do not. 9 Q. Okay. Get back to your CV in a 10 moment. 11 You're a medical doctor? 12 A. I am. 13 Q. And you're board certified in 14 internal medicine? 15 A. Internal medicine, pulmonary 16 medicine and critical care medicine. 17 Q. Okay. And you are also an 18 associate professor of medicine in the 19 Department of Pulmonary and Critical Care 20 Medicine at Johns Hopkins University? 21 A. In the department of medicine 22 and also in the department of epidemiology at 23 the School of Public Health. 24 Q. I'll ask you about the second 25 later, but my specific question is that you</p>
<p style="text-align: right;">Page 11</p> <p>1 oath to the witness. 2 3 CHRISTIAN MERLO, M.D., MPH, 4 of lawful age, having been first duly sworn 5 to tell the truth, the whole truth and 6 nothing but the truth, deposes and says on 7 behalf of the Plaintiffs, as follows: 8 9 (Merlo Exhibit 1 marked for 10 identification.) 11 12 DIRECT EXAMINATION 13 QUESTIONS BY MR. TISI: 14 Q. Please state your name. 15 A. My name is Christian Merlo. 16 Q. And I've placed before you, 17 Dr. Merlo, a copy of your CV as Exhibit 1. 18 Do you see that? 19 A. I do. 20 Q. Is this your current CV? 21 This was produced to us in 22 connection with this litigation. 23 A. Seems about right. 24 Q. Okay. Is there anything that 25 needs to be added to it since February of</p>	<p style="text-align: right;">Page 13</p> <p>1 are associate professor of medicine in the 2 Department of Pulmonary and Critical Care 3 Medicine at Johns Hopkins University? 4 A. But my official title is an 5 associate professor of medicine in 6 epidemiology. 7 (Merlo Exhibit 2 marked for 8 identification.) 9 QUESTIONS BY MR. TISI: 10 Q. Okay. I would like you show 11 you what I would like to have marked as 12 Exhibit Number 2. 13 This is the -- 14 MR. TISI: I'm sorry, did you 15 put an exhibit sticker on it? 16 QUESTIONS BY MR. TISI: 17 Q. This is the web page to the 18 Johns Hopkins Division of Pulmonary and 19 Critical Care Medicine. 20 Do you see that? 21 A. I see the exhibit, yes. 22 Q. Okay. And who is Nadia Hansel? 23 A. Nadia Hansel is our current 24 division director of the pulmonary and 25 critical care division.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 14</p> <p>1 Q. She basically runs your 2 division?</p> <p>3 A. Well, she's part of the crew 4 that runs the division, but she's our 5 division director.</p> <p>6 Q. Okay. And did you see where it 7 describes -- on the second paragraph it 8 describes the scope of conditions treated in 9 the department, Division of Pulmonary and 10 Critical Care Medicine?</p> <p>11 A. I see that paragraph, yes.</p> <p>12 Q. Let me read it for the record. 13 It says, "We hold clinical and 14 research expertise in a broad range of 15 diseases, including asthma, COPD, critical 16 care, cystic fibrosis, interstitial lung 17 disease, lung cancer, lung transplantation, 18 neuromuscular disease, pulmonary 19 hypertension, sarcoidosis and sleep 20 medicine."</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Does the Johns Hopkins Division 24 of Pulmonary and Critical Care Medicine 25 provide primary care treatment for</p>	<p style="text-align: right;">Page 16</p> <p>1 care of patients like that.</p> <p>2 Q. Okay. So -- I'm sorry. I 3 didn't mean to interrupt you.</p> <p>4 So other than treating the side 5 effects that perhaps might occur in the 6 context of a patient who has gynecologic 7 cancers, people with ovarian cancer typically 8 are treated by oncologists; is that true? 9 Primarily?</p> <p>10 A. Again, if we're talking about 11 oncologic therapy, yes, they would be 12 traditionally treated by oncologists.</p> <p>13 Q. You're what's called an 14 associate professor?</p> <p>15 A. I am an associate professor.</p> <p>16 Q. Okay. And just to follow up on 17 the last question, you're not board certified 18 in oncology, are you?</p> <p>19 A. I'm not.</p> <p>20 Q. Do you have tenure?</p> <p>21 A. Tenure is a tricky thing at 22 Hopkins. There's not really a full 23 definition of it.</p> <p>24 The usual definition is if 25 you're asked to stay after an instructor, the</p>
<p style="text-align: right;">Page 15</p> <p>1 gynecologic cancers?</p> <p>2 A. I think you'd have to define 3 primary care treatment.</p> <p>4 Q. Yes.</p> <p>5 A. We do have an oncologic center 6 where we take care of many patients who are 7 very, very sick with cancers, and some of 8 those involve gynecologic cancers, and we are 9 the primary caregiver in our onc ICU.</p> <p>10 Q. Okay. But is that in the 11 Division of Pulmonary and Critical Care --</p> <p>12 A. Yes.</p> <p>13 Q. -- Medicine?</p> <p>14 Okay. But the treatment of 15 people who actually are diagnosed, until the 16 very end of their treatment, is not in your 17 division; is that correct?</p> <p>18 A. Again, I think you'd have to 19 define what the treatment is --</p> <p>20 Q. Okay.</p> <p>21 A. -- because sometimes the 22 treatment involved in gynecologic cancers 23 involves therapies that give side effects, 24 and those side effects land those patients in 25 some intensive care units where we do take</p>	<p style="text-align: right;">Page 17</p> <p>1 institution is committed to keeping you here.</p> <p>2 Q. Okay.</p> <p>3 A. But there's no contract that 4 one signs or that one gets saying "you can 5 stay here forever."</p> <p>6 Q. You're not a full professor?</p> <p>7 A. I am not a full professor.</p> <p>8 Q. And your expertise is critical 9 care -- is in the care -- critical care -- 10 I'm sorry.</p> <p>11 Your expertise has been 12 described as in critical care and cystic 13 fibrosis, and those with lung transplants as 14 well as patients who have other lung 15 diseases, as well as those who require 16 critical care therapy.</p> <p>17 Is that true?</p> <p>18 MS. MILLER: Objection.</p> <p>19 Are you looking at this?</p> <p>20 MR. TISI: I'm not -- you can 21 object.</p> <p>22 THE WITNESS: No, you'd have to 23 show me where you're getting that. I 24 mean, I have lots of expertise. I 25 have expertise in internal medicine</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 18</p> <p>1 and a broad range of pulmonary 2 medicine, a broad range of critical 3 care medicine as well as lung 4 transplantation. 5 So I'm not sure where you got 6 that from, but if you show me 7 something I can -- 8 QUESTIONS BY MR. TISI: 9 Q. We'll do that. 10 I think you mentioned you don't 11 hold yourself out as an expert in oncology, 12 correct? 13 MS. MILLER: Objection. 14 THE WITNESS: I think what I 15 said before is I do have a broad range 16 of experience in taking care of 17 oncologic patients in our oncology 18 ICU, so I do consider myself an expert 19 in the intensive care unit care for 20 patients with oncologic disease. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. Different question, 23 however. 24 Do you hold yourself out to 25 your colleagues as an expert -- as a cancer</p>	<p style="text-align: right;">Page 20</p> <p>1 Do you see that? 2 A. I do. 3 Q. And you identify, if I'm 4 reading correctly, 79 peer-reviewed papers? 5 A. Seems about right. 6 Q. Do any of your peer-reviewed 7 papers deal with gynecologic cancers? 8 A. There's one paper where we look 9 at the risk of malignancy after lung 10 transplantation, and I believe we looked at 11 certain -- I have to go back and look at the 12 paper, but I believe we looked at all sorts 13 of cancers, and gynecologic cancers may have 14 been in there as well. 15 Q. But the focus of the paper was 16 the consequences of lung transplantation, 17 correct? 18 A. The risk of malignancy after 19 lung transplantation. 20 Q. Do any of them deal 21 specifically with ovarian cancer and its 22 causes? 23 A. No. 24 Q. Do any of them deal with talcum 25 powder products?</p>
<p style="text-align: right;">Page 19</p> <p>1 expert? 2 MS. MILLER: Objection. 3 THE WITNESS: I'm going to have 4 to say the same thing, because part of 5 cancer does deal with patients who get 6 very, very, very sick. And as a 7 group, we have several in our group 8 who attend in our oncology ICU, and 9 I'm one of them, and I do have 10 specific expertise in that aspect of 11 oncology. 12 QUESTIONS BY MR. TISI: 13 Q. And you are not board certified 14 in oncology, however? 15 A. I believe I said I wasn't. 16 Q. And you're not a gynecologist? 17 A. I'm not a gynecologist. 18 Q. You're not a toxicologist? 19 A. I am not a toxicologist. 20 Q. You're not a mineralogist? 21 A. I'm not a mineralogist. 22 Q. Turning back to your CV, 23 Exhibit 1, page 2, you have a section 24 entitled "Peer Review, Original Science 25 Publications."</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Excuse me. No. 2 Q. Do any of them deal with 3 asbestos? 4 A. No. 5 Q. In fact, you understand in this 6 case that there is a claim that there is 7 asbestos contamination or asbestos included 8 in talcum powder products, correct? 9 MS. MILLER: Objection. 10 THE WITNESS: I wasn't asked to 11 give an opinion on asbestos in this 12 case. 13 QUESTIONS BY MR. TISI: 14 Q. Okay. And I understand that, 15 and that was going to be my question. So I'm 16 going to ask you that you -- so we don't run 17 into problems here, I'm going to ask that you 18 listen to my question. Okay? 19 Do you understand that there is 20 an allegation in this case -- and if you 21 don't have an understanding, that's fine -- 22 that there is asbestos in talc -- Johnson & 23 Johnson's talcum powder products? 24 MS. MILLER: Objection. 25 MR. LOCKE: Objection.</p>

6 (Pages 18 to 21)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 22</p> <p>1 THE WITNESS: Again, I wasn't</p> <p>2 asked to give an opinion about</p> <p>3 asbestos.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. I didn't ask whether you were</p> <p>6 asked to give opinions.</p> <p>7 Do you have any understanding</p> <p>8 if that's part of the record in this case?</p> <p>9 MS. MILLER: Same objections.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. That's fine.</p> <p>13 So again, I'm going to ask you</p> <p>14 to listen to my question.</p> <p>15 So you're not offering an</p> <p>16 opinion as to whether or not talc -- the</p> <p>17 presence or -- the presence of asbestos</p> <p>18 provides a biologically plausible mechanism</p> <p>19 for talcum powder product causing ovarian</p> <p>20 cancer?</p> <p>21 A. So I have not reviewed the</p> <p>22 literature specifically about asbestos. I</p> <p>23 was not asked to provide an opinion about</p> <p>24 asbestos.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 24</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Yes.</p> <p>3 Were you asked to provide an</p> <p>4 opinion as to whether or not the presence of</p> <p>5 asbestos in talcum powder products is a</p> <p>6 biologically plausible mechanism for causing</p> <p>7 ovarian cancer?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I was asked to</p> <p>11 provide an opinion on talcum powder</p> <p>12 products. And my opinion, based on</p> <p>13 the epidemiologic literature, is that</p> <p>14 there is no causal association.</p> <p>15 So whatever is in talcum powder</p> <p>16 products would have come out in the</p> <p>17 literature.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Okay. Would it be fair to say</p> <p>20 you've never published any commentary or</p> <p>21 review of the literature on ovarian cancer</p> <p>22 and its causes generally? I apologize.</p> <p>23 A. I have never published a review</p> <p>24 on ovarian cancer.</p> <p>25 Q. Have you published a review on</p>
<p style="text-align: right;">Page 23</p> <p>1 A. However, if asbestos was</p> <p>2 present at all in a sufficient dose within</p> <p>3 talcum powder products, that would have come</p> <p>4 out in the epidemiologic literature, which it</p> <p>5 didn't.</p> <p>6 Q. Okay.</p> <p>7 A. Because the epidemiology shows</p> <p>8 that there is not a causal association</p> <p>9 between talcum powder and ovarian cancer.</p> <p>10 MR. TISI: I'm going to move to</p> <p>11 strike the answer as nonresponsive.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. My question was: Were you</p> <p>14 asked to offer a -- by the way, I'm not</p> <p>15 getting any -- I said -- my question was:</p> <p>16 Did you -- were you asked whether or not the</p> <p>17 presence of asbestos would provide a</p> <p>18 biologically plausible mechanism for talcum</p> <p>19 powder products causing ovarian cancer?</p> <p>20 The question is either yes or</p> <p>21 no.</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: Can you ask that</p> <p>24 question again?</p> <p>25</p>	<p style="text-align: right;">Page 25</p> <p>1 any cancer?</p> <p>2 A. We have a review in press --</p> <p>3 sorry, in submission on malignancies after</p> <p>4 lung transplantation.</p> <p>5 Q. Does it focus on whether or not</p> <p>6 talcum powder products is a risk factor for</p> <p>7 ovarian cancer?</p> <p>8 A. It does not.</p> <p>9 Q. Have you ever published a</p> <p>10 commentary or review on the causes of ovarian</p> <p>11 cancer?</p> <p>12 A. I have not.</p> <p>13 Q. Have you published a commentary</p> <p>14 or review on talcum powder products and its</p> <p>15 safety?</p> <p>16 A. I have not.</p> <p>17 Q. Have you published any</p> <p>18 commentary or review that deal with lifestyle</p> <p>19 or environmental cause of disease?</p> <p>20 MS. MILLER: Objection.</p> <p>21 THE WITNESS: That's a pretty</p> <p>22 broad question.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. It is.</p> <p>25 A. I mean, you have my CV here,</p>

7 (Pages 22 to 25)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 26</p> <p>1 and my clinical and research experience has</p> <p>2 dealt with epidemiology. And the</p> <p>3 epidemiology -- epidemiology usually is the</p> <p>4 study of an exposure and how it relates to an</p> <p>5 outcome, and most of my papers and research</p> <p>6 has focused on exposures and how they lead to</p> <p>7 outcomes.</p> <p>8 Q. So what exposures,</p> <p>9 environmental or lifestyle exposures, have</p> <p>10 you investigated as related to what diseases?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Well, you'd have</p> <p>13 to get a little more specific about</p> <p>14 what diseases we're talking about.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. So my question was a broad one,</p> <p>17 because I don't see anything in your</p> <p>18 published literature that falls in this</p> <p>19 category, but it may just be that I missed</p> <p>20 it.</p> <p>21 Do you have any articles which</p> <p>22 deal with the relationship between lifestyle</p> <p>23 and environmental factors and any kind of</p> <p>24 cancer?</p> <p>25 A. That's a different question.</p>	<p style="text-align: right;">Page 28</p> <p>1 continue. So that environmental exposure can</p> <p>2 lead to an outcome over time.</p> <p>3 Q. But did you study the</p> <p>4 relationship between the exposure and the</p> <p>5 outcome, or was it primarily focused on lung</p> <p>6 transplant?</p> <p>7 A. Well, I --</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Let me rephrase the question.</p> <p>11 Let me withdraw and rephrase the question.</p> <p>12 Did you do any causation</p> <p>13 analysis, including applying the Bradford</p> <p>14 Hill factors, to any exposure and any cancer</p> <p>15 in any of your publications?</p> <p>16 A. So in general, when a study is</p> <p>17 performed, we try to do either a Bradford</p> <p>18 Hill or different aspects of Bradford Hill to</p> <p>19 look at strength of associations or look at</p> <p>20 specificity, to look at consistency, to look</p> <p>21 at dose response. Sometimes it's available;</p> <p>22 sometimes it's not.</p> <p>23 I think it's a -- it's a --</p> <p>24 it's a framework that is often used in these</p> <p>25 papers and in these studies, but it's not</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Okay. So the answer would be?</p> <p>2 A. Well, I would have to say that</p> <p>3 the risk of malignancy after lung</p> <p>4 transplantation does deal with that.</p> <p>5 Q. Is lung transplantation an</p> <p>6 environmental or lifestyle?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: So again, that's</p> <p>9 a pretty broad question. It can be --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay.</p> <p>12 A. -- and it depends, because a</p> <p>13 lung transplant could be done for someone who</p> <p>14 is born with a disease, say like cystic</p> <p>15 fibrosis, a genetic disease, or a lung</p> <p>16 transplantation could be performed because</p> <p>17 someone has emphysema because they smoked all</p> <p>18 their life.</p> <p>19 And so the environmental</p> <p>20 exposure and the personal health exposure is</p> <p>21 very, very different in those two</p> <p>22 populations.</p> <p>23 Someone who's smoking may</p> <p>24 smoke -- continue to smoke after their lung</p> <p>25 transplant. It's not advised, but they may</p>	<p style="text-align: right;">Page 29</p> <p>1 necessarily the only thing that's done in</p> <p>2 them.</p> <p>3 Q. I understand.</p> <p>4 But if I looked at -- and I</p> <p>5 appreciate that. These may touch on aspects</p> <p>6 of Brad Hill -- the Bradford Hill guidelines.</p> <p>7 My question is: Did you ever,</p> <p>8 in any of these papers, synthesize all of the</p> <p>9 medical and scientific information available</p> <p>10 in order to do a Bradford Hill, complete</p> <p>11 Bradford Hill, analysis of the relationship</p> <p>12 between an exposure and a disease?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Well, that's a</p> <p>15 very, very, very broad question.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Uh-huh.</p> <p>18 A. I think that there are certain</p> <p>19 papers in my CV that -- studies that we've</p> <p>20 done. It's the only study available that we</p> <p>21 did.</p> <p>22 Q. Okay.</p> <p>23 A. So, you know, it's impossible</p> <p>24 to synthesize everything that's in the</p> <p>25 medical literature if it's the only study</p>

Christian Merlo, M.D., MPH

Page 30	Page 32
<p>1 that's done.</p> <p>2 Q. Okay. So if I -- it wouldn't</p> <p>3 be surprising if I looked at all these papers</p> <p>4 and the word "Bradford Hill" does not appear</p> <p>5 in any of them?</p> <p>6 A. That wouldn't be something that</p> <p>7 would appear --</p> <p>8 Q. Okay.</p> <p>9 A. -- normally in a paper like</p> <p>10 this.</p> <p>11 Q. Do any of these 78, 79 papers</p> <p>12 purport to provide any guidance or discussion</p> <p>13 of the definition or how to apply the</p> <p>14 Bradford Hill criteria, a theoretic paper,</p> <p>15 for example?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: I don't have any</p> <p>18 theoretical papers describing a</p> <p>19 Bradford Hill analysis.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. So just -- this is a</p> <p>22 slightly different question than before.</p> <p>23 Have you ever published</p> <p>24 research aimed at elucidating a possible</p> <p>25 causation between a putative risk factor and</p>	<p>1 where you identified a risk factor for a</p> <p>2 disease?</p> <p>3 A. I can.</p> <p>4 I mean, one of the first</p> <p>5 studies that we did was to look at the risk</p> <p>6 factors for developing resistant bacteria in</p> <p>7 patients with cystic fibrosis.</p> <p>8 Q. Okay. In that context, did you</p> <p>9 apply the Bradford Hill guidelines?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Again, that's not</p> <p>12 really something that would have been</p> <p>13 done in that study.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay.</p> <p>16 A. There's a -- there's a large</p> <p>17 epidemiologic data set that the Cystic</p> <p>18 Fibrosis Foundation has, and we utilized that</p> <p>19 to identify factors that we thought might be</p> <p>20 important in seeing if those factors led to</p> <p>21 this resistant organism in that population.</p> <p>22 (Merlo Exhibit 3 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. I'm going to mark your report</p>
Page 31	Page 33
<p>1 disease?</p> <p>2 A. Well, I think that -- can you</p> <p>3 ask that again?</p> <p>4 Q. Yes.</p> <p>5 Have you ever published</p> <p>6 research aimed at elucidating possible</p> <p>7 causation between a putative risk factor and</p> <p>8 a disease?</p> <p>9 MS. MILLER: I'm objecting.</p> <p>10 Objection.</p> <p>11 THE WITNESS: So it's not -- we</p> <p>12 don't really approach epidemiologic</p> <p>13 studies trying to show causation with</p> <p>14 risk factors.</p> <p>15 Sometimes there are studies</p> <p>16 that are -- that we do just to</p> <p>17 identify risk factors. And then once</p> <p>18 risk factors are identified, then we</p> <p>19 could do follow-up studies to see if</p> <p>20 they are actual factors or exposures</p> <p>21 that lead to a certain outcome.</p> <p>22 Sometimes that takes multiple</p> <p>23 studies to do that.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Can you identify an article</p>	<p>1 in this case.</p> <p>2 You issued a report in the</p> <p>3 talcum powder products litigation?</p> <p>4 A. I wrote a report.</p> <p>5 Q. Yes.</p> <p>6 A. Yes, I did.</p> <p>7 Q. Marked as Exhibit Number 3.</p> <p>8 A. Thank you.</p> <p>9 Q. Uh-huh.</p> <p>10 I think we've also been</p> <p>11 provided a supplemental materials reviewed</p> <p>12 and considered paper which I'll mark as 3A,</p> <p>13 which I assume is a supplement to your</p> <p>14 report.</p> <p>15 (Merlo Exhibit 3A marked for</p> <p>16 identification.)</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Is this your report in this</p> <p>19 case, and are these the supplemental</p> <p>20 materials you reviewed as of today?</p> <p>21 A. This looks about correct.</p> <p>22 Q. Okay. Does this contain all</p> <p>23 the opinions you're prepared to offer in this</p> <p>24 case?</p> <p>25 MS. MILLER: Objection.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 34</p> <p>1 THE WITNESS: From the -- from</p> <p>2 the items that I've reviewed thus far.</p> <p>3 There may be other things that come up</p> <p>4 in the literature, there may be other</p> <p>5 reports that are out, and I would like</p> <p>6 to review those and...</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. But as of today, as of today,</p> <p>9 this is -- these are your opinions and these</p> <p>10 are the bases of your opinions, correct?</p> <p>11 A. They are.</p> <p>12 Q. Okay. Go to page 30 of your</p> <p>13 report, if you would. The second sentence of</p> <p>14 your report says, "While there is no single</p> <p>15 method for undertaking a causal assessment</p> <p>16 based on epidemiology, the criteria</p> <p>17 formulated by Austin Bradford Hill are often</p> <p>18 used and are considered the gold standard for</p> <p>19 evaluating causation once an association has</p> <p>20 been identified."</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Can you point to any articles</p> <p>24 on your CV where you applied the gold</p> <p>25 standard articulated on page 30 of your</p>	<p style="text-align: right;">Page 36</p> <p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I wouldn't say it</p> <p>3 that way.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. I understand you wouldn't say</p> <p>6 it that way, but in concept.</p> <p>7 A. In concept.</p> <p>8 That's the concept of all of</p> <p>9 those articles, or at least the majority of</p> <p>10 them, that we're looking for -- we're looking</p> <p>11 at an outcome, and we're looking for an</p> <p>12 exposure to see if that exposure leads to an</p> <p>13 outcome.</p> <p>14 And there are considerations</p> <p>15 that we consciously or subconsciously -- "we"</p> <p>16 meaning my research team and myself</p> <p>17 consciously and subconsciously --</p> <p>18 considerations that Bradford Hill put forth</p> <p>19 that we apply in there.</p> <p>20 Now, is it stated? No, but it</p> <p>21 wouldn't be stated in the papers. The</p> <p>22 medical literature is not written that like</p> <p>23 that.</p> <p>24 Q. Okay. You mentioned -- and you</p> <p>25 give an example in your report; we're going</p>
<p style="text-align: right;">Page 35</p> <p>1 report?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: Well, again, most</p> <p>4 of these articles are epidemiologic</p> <p>5 studies looking at an exposure and an</p> <p>6 outcome.</p> <p>7 Sometimes there are Bradford</p> <p>8 Hill considerations that are</p> <p>9 available, and sometimes there are</p> <p>10 not.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. But whether they are -- I'm</p> <p>13 sorry, go ahead.</p> <p>14 A. And in every study, we apply</p> <p>15 what we can --</p> <p>16 Q. Right.</p> <p>17 A. -- based on these suggestions</p> <p>18 put forth by Bradford Hill.</p> <p>19 Q. Is there any study in which you</p> <p>20 say, "We are undertaking" -- and I'm not</p> <p>21 using these words specifically.</p> <p>22 "We are, in this article,</p> <p>23 undertaking a causal assessment of putative</p> <p>24 factor X and disease Y, and here is my</p> <p>25 analysis"?</p>	<p style="text-align: right;">Page 37</p> <p>1 to talk about it later -- primary pulmonary</p> <p>2 hypertension and anorexigens.</p> <p>3 Do you remember the IPPHS</p> <p>4 study?</p> <p>5 A. I do.</p> <p>6 Q. Does, in your opinion, exposure</p> <p>7 to anorexigens cause pulmonary hypertension,</p> <p>8 primary pulmonary hypertension?</p> <p>9 A. The opinion of the medical</p> <p>10 community -- and part of that is that a</p> <p>11 significant exposure over a significant</p> <p>12 amount of time with certain specific</p> <p>13 anorexigens is associated with pulmonary</p> <p>14 hypertension.</p> <p>15 Q. That's a different -- that's a</p> <p>16 different question than I'm asking, Doctor.</p> <p>17 So I asked you -- I asked you</p> <p>18 whether or not in your opinion exposure to</p> <p>19 anorexigens, in particular dexfenfluramine</p> <p>20 and fenfluramine, cause pulmonary</p> <p>21 hypertension?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: So I'm going to</p> <p>24 answer it very similarly, because</p> <p>25 you --</p>

Christian Merlo, M.D., MPH

Page 38	Page 40
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. But I'm using the word "cause,"</p> <p>3 so --</p> <p>4 A. And based on the medical</p> <p>5 literature and based on clinical experience,</p> <p>6 if we're talking about those two anorexigens,</p> <p>7 the opinion of the medical community is that</p> <p>8 those cause primary pulmonary hypertension.</p> <p>9 Q. Okay. Is that your opinion?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And we'll talk about it</p> <p>12 again, but there was only one study,</p> <p>13 epidemiologic study, the IPPHS study,</p> <p>14 correct?</p> <p>15 A. You'd have to show me what</p> <p>16 you're referring to so we can look at it.</p> <p>17 Q. Yeah, it's the study by</p> <p>18 Abenheim. I believe it's footnote 77 of your</p> <p>19 report.</p> <p>20 You know that study, don't you?</p> <p>21 A. I referenced it, but if you'd</p> <p>22 like to discuss it --</p> <p>23 Q. I'm not going to discuss --</p> <p>24 A. -- I'd like to see it in front</p> <p>25 of me to discuss it.</p>	<p>1 hypertension expert, so if you'd like to</p> <p>2 discuss that, I would need to review the</p> <p>3 medical literature.</p> <p>4 Q. Okay.</p> <p>5 A. I can't agree or disagree with</p> <p>6 you.</p> <p>7 Q. Well, you're not an ovarian</p> <p>8 cancer expert, are you?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I think I</p> <p>11 answered that before.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. If you're not a primary</p> <p>14 pulmonary hypertension expert, and that's a</p> <p>15 lung disease, are you a -- do you consider</p> <p>16 yourself an ovarian cancer expert?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: And what I said</p> <p>19 before is that there are certain</p> <p>20 aspects of cancer that I do consider</p> <p>21 myself an expert, and that is the care</p> <p>22 of patients who have cancer in the</p> <p>23 intensive care unit.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Okay. Do you hold yourself out</p>
Page 39	Page 41
<p>1 Q. I will discuss it later and</p> <p>2 I'll -- I will discuss it later, but I'm</p> <p>3 asking you: Do you know that there was only</p> <p>4 one study, epidemiologic study, performed?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: I'm not aware of</p> <p>7 that, but if we're going to talk about</p> <p>8 studies, then I would have like to</p> <p>9 have that in front of me.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I'm going to give it to you.</p> <p>12 I'm asking you whether there</p> <p>13 are any other studies, epidemiologic studies,</p> <p>14 that you're aware of other than that study,</p> <p>15 which I will give you.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: You know, I'm not</p> <p>19 really here to give my opinion on</p> <p>20 whether or not there was one or ten</p> <p>21 epidemiologic studies looking at</p> <p>22 anorexigens in pulmonary hypertension.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. I understand.</p> <p>25 A. I'm not a pulmonary</p>	<p>1 to your colleagues as an expert in ovarian</p> <p>2 cancer?</p> <p>3 MS. MILLER: Objection.</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: I'm going to have</p> <p>6 to answer that very similarly because</p> <p>7 there are certain aspects of</p> <p>8 malignancies where I have taken care</p> <p>9 of patients with ovarian cancer in the</p> <p>10 intensive care unit, who are very,</p> <p>11 very sick, who have been given</p> <p>12 specific therapies for their ovarian</p> <p>13 cancer, that I do consider myself an</p> <p>14 expert in taking care of.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I understand that.</p> <p>17 But ovarian cancer is a -- let</p> <p>18 me just -- if I was, you know, a doctor at</p> <p>19 Hopkins, and we're not sitting here in a</p> <p>20 deposition, and I came to you and said,</p> <p>21 "Doctor, what is your area of expertise?"</p> <p>22 would you say "ovarian cancer"?</p> <p>23 MS. MILLER: Objection.</p> <p>24 MR. LOCKE: Objection. Asked</p> <p>25 and answered four times.</p>

Christian Merlo, M.D., MPH

Page 42	Page 44
<p>1 THE WITNESS: I would say</p> <p>2 internal medicine. I would say</p> <p>3 pulmonary medicine. I would say</p> <p>4 critical care medicine. And all of</p> <p>5 those -- well, maybe -- no, actually</p> <p>6 all of them encompass taking care of</p> <p>7 patients who can become or do become</p> <p>8 very, very sick with ovarian cancer</p> <p>9 and with specific -- and having</p> <p>10 specific expertise in taking care of</p> <p>11 some of the medicines that they get</p> <p>12 that give them very, very specific</p> <p>13 side effects.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Have you also cared for</p> <p>16 patients with primary pulmonary hypertension?</p> <p>17 A. I have.</p> <p>18 Q. Okay. So does that also make</p> <p>19 you an expert in the area of primary</p> <p>20 pulmonary hypertension?</p> <p>21 A. So there are certain aspects of</p> <p>22 primary pulmonary hypertension that I do</p> <p>23 consider myself an expert in. I do take care</p> <p>24 of patients in the hospital who have primary</p> <p>25 pulmonary hypertension and also secondary</p>	<p>1 the market for quite some time, so it</p> <p>2 would be very rare to see somebody who</p> <p>3 had a new diagnosis of pulmonary</p> <p>4 hypertension and an exposure to one of</p> <p>5 those medicines.</p> <p>6 When I'm evaluating someone</p> <p>7 with pulmonary hypertension, I</p> <p>8 typically do ask them about the</p> <p>9 potential exposures to anorexigens.</p> <p>10 It's just on the list of things to do.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. And it should be part of the</p> <p>14 differential diagnosis.</p> <p>15 Q. So you're treating -- is it</p> <p>16 fair to say that with ovarian cancer you're</p> <p>17 treating the sequela of the disease, not</p> <p>18 making the diagnosis of the disease?</p> <p>19 A. No, I mean, I've probably made</p> <p>20 the diagnosis of disease one or two times in</p> <p>21 my career.</p> <p>22 Q. Okay. And how long -- when you</p> <p>23 say your career, how long is that?</p> <p>24 A. I graduated medical school in</p> <p>25 1996, so that's when I became a doctor.</p>
Page 43	Page 45
<p>1 pulmonary hypertension.</p> <p>2 But -- I'll just stop there.</p> <p>3 Q. Do you put -- when you're</p> <p>4 taking care of a patient with primary</p> <p>5 pulmonary hypertension and they're exposed to</p> <p>6 anorexigens, or they're exposed to</p> <p>7 fenfluramine, dexfenfluramine, although those</p> <p>8 are off the market, and would you note that</p> <p>9 on the list of potential differential causes</p> <p>10 of the pulmonary hypertension?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Can you ask that</p> <p>13 again?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 If you have a patient who has</p> <p>17 primary pulmonary hypertension with a history</p> <p>18 of use of the anorexigens fenfluramine and</p> <p>19 dexfenfluramine, do you put them on the list</p> <p>20 of potential causes in your -- do you make</p> <p>21 note of that in your record?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Well, you're</p> <p>25 right, these medicines have been off</p>	<p>1 Q. Okay. So can you -- you list</p> <p>2 the factors on page 30 of your report, the</p> <p>3 Bradford Hill factors: strength of</p> <p>4 association, consistency, specificity,</p> <p>5 temporality, biologic gradient, plausibility,</p> <p>6 coherence, experimentation, analogy.</p> <p>7 You list them all, correct?</p> <p>8 A. One, two, three, four, five,</p> <p>9 six, seven, eight, nine. Yes, correct.</p> <p>10 Q. Okay. From the time that</p> <p>11 Bradford Hill, Sir Bradford Hill, wrote his</p> <p>12 article -- and you agree that's a seminal</p> <p>13 paper on the topic of how you evaluate cause?</p> <p>14 A. It's an article, and it's an</p> <p>15 important article historically. We learn</p> <p>16 about it in epidemiology classes. I teach</p> <p>17 about it.</p> <p>18 Seminal article, I mean, there</p> <p>19 are lots of articles that are written about</p> <p>20 causation. This is an article that I've</p> <p>21 learned about in class and I've taught about</p> <p>22 in class.</p> <p>23 Q. Well, I think you used the word</p> <p>24 "seminal" in your report, didn't you?</p> <p>25 A. I may have.</p>

12 (Pages 42 to 45)

Christian Merlo, M.D., MPH

Page 46	Page 48
<p>1 Q. Okay.</p> <p>2 A. If you can show me that, I --</p> <p>3 Q. So, well, do you agree that</p> <p>4 it's --</p> <p>5 A. I don't know where.</p> <p>6 Q. -- it's a seminal article on</p> <p>7 the issue?</p> <p>8 A. But can you show me where I</p> <p>9 said that?</p> <p>10 Q. I'm asking what your opinion</p> <p>11 is as to whether or not you agree that's the</p> <p>12 seminal article -- that's a seminal article</p> <p>13 on causation.</p> <p>14 A. But you said I --</p> <p>15 Q. I'm not asking you whether you</p> <p>16 said it in the report.</p> <p>17 A. You just did.</p> <p>18 MS. MILLER: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. I'm asking you -- I'm asking</p> <p>21 you whether it is a seminal article.</p> <p>22 A. And I'll say, it's -- it is an</p> <p>23 article about -- written about causation.</p> <p>24 Q. Okay. Has the medical</p> <p>25 community, over the past 60 years, changed</p>	<p>1 I'm asking you: In your</p> <p>2 view -- let me -- in terms of you, Dr. Merlo,</p> <p>3 do you apply the same -- is your definitions</p> <p>4 of the Bradford Hill factors the same in 2019</p> <p>5 as described by Bradford Hill in 1965?</p> <p>6 A. I would say that it's very</p> <p>7 similar --</p> <p>8 Q. Okay.</p> <p>9 A. -- to what's described.</p> <p>10 Q. Is there any that are different</p> <p>11 in your view?</p> <p>12 Can you look at it and say, for</p> <p>13 example, "My view of the coherence factor is</p> <p>14 different than as described by Dr. -- by</p> <p>15 Bradford Hill"?</p> <p>16 MS. MILLER: Objection.</p> <p>17 For the record, I'll just state</p> <p>18 that the -- Dr. Merlo brought Bradford</p> <p>19 Hill with him.</p> <p>20 MR. TISI: I'm going to mark it</p> <p>21 as well.</p> <p>22 MS. MILLER: Do you want to</p> <p>23 mark this one?</p> <p>24 MR. TISI: I will not. I'll</p> <p>25 mark them when I get --</p>
Page 47	Page 49
<p>1 the definitions of any of the Bradford Hill</p> <p>2 factors as described by Bradford Hill in his</p> <p>3 1965 article?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: That is a very</p> <p>6 general question, and I would have to</p> <p>7 say that it depends. It depends on</p> <p>8 who you're defining as the medical</p> <p>9 community, who you're defining as --</p> <p>10 yeah, I mean, that's a -- too general</p> <p>11 a question to answer.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Well, are there different --</p> <p>14 do -- does the medical community define these</p> <p>15 factors differently depending upon who's</p> <p>16 applying them?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: Again, I don't</p> <p>19 know who you're referring to as far as</p> <p>20 the medical community. You'd have to</p> <p>21 be much more specific about that.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Well, you used the term,</p> <p>24 Doctor. I'm just kind of jumping off of what</p> <p>25 you said.</p>	<p>1 MS. MILLER: But he's looking</p> <p>2 at it now.</p> <p>3 MR. TISI: He can look at it.</p> <p>4 I think you're limited to "objection,"</p> <p>5 and if we start with this, we're going</p> <p>6 to go to the judge.</p> <p>7 MS. SHARKO: Mr. Tisi --</p> <p>8 MR. TISI: And that's another</p> <p>9 thing. We're only having one</p> <p>10 objection.</p> <p>11 MS. SHARKO: You don't need to</p> <p>12 point your finger.</p> <p>13 MR. TISI: I pointed up. I</p> <p>14 pointed up, Counsel, and the record</p> <p>15 will reflect that I did. There's a</p> <p>16 camera right on me, as you assured me.</p> <p>17 And you're laughing, let the</p> <p>18 record reflect that, as you do in</p> <p>19 every deposition.</p> <p>20 MS. SHARKO: Please, behave</p> <p>21 yourself.</p> <p>22 MR. TISI: Agreed.</p> <p>23 THE WITNESS: So did you have a</p> <p>24 specific question about coherence?</p> <p>25</p>

13 (Pages 46 to 49)

Christian Merlo, M.D., MPH

Page 50	Page 52
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. No.</p> <p>3 My question is -- I want to be</p> <p>4 able to say -- I want to know whether or not</p> <p>5 your 2009 {sic} definitions of the Bradford</p> <p>6 Hill factors -- no, let me phrase it a</p> <p>7 different way.</p> <p>8 Do you take any issue with any</p> <p>9 of the factors as described in the 1965</p> <p>10 articles and say, you know, "This concept is</p> <p>11 outdated, I would define it differently," or</p> <p>12 can we look at the 1965 factors as being the</p> <p>13 ones you actually apply, the definitions you</p> <p>14 use?</p> <p>15 A. So I usually look at them as</p> <p>16 considerations and not factors.</p> <p>17 Q. Okay.</p> <p>18 A. And in general, the way it's</p> <p>19 written is how I interpret and move through</p> <p>20 when I evaluate evidence.</p> <p>21 Q. Okay. Now, almost every one of</p> <p>22 your 79 peer-reviewed papers going back to</p> <p>23 your CV have to do with lung disease of one</p> <p>24 kind or another, correct?</p> <p>25 A. There are a few that deal with</p>	<p>1 MS. MILLER: Objection.</p> <p>2 MR. LOCKE: Objection.</p> <p>3 MS. MILLER: Asked and answered</p> <p>4 again.</p> <p>5 THE WITNESS: I mean, I don't</p> <p>6 even know what vast majority means,</p> <p>7 but --</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. I would say -- let's say more</p> <p>10 than 50 percent.</p> <p>11 MS. MILLER: Objection to the</p> <p>12 definition of "vast majority" as more</p> <p>13 than 50 percent.</p> <p>14 THE WITNESS: So, again, I</p> <p>15 don't know the numbers. We can go</p> <p>16 through them if you'd like --</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. -- and get a percentage, but --</p> <p>20 Q. I think -- I think -- fine.</p> <p>21 On your CV at the bottom of</p> <p>22 page 8 you've written several book chapters,</p> <p>23 correct?</p> <p>24 A. Book chapters, sure.</p> <p>25 Q. Do any deal with cancer?</p>
Page 51	Page 53
<p>1 certain conditions that may not involve lung</p> <p>2 disease.</p> <p>3 Q. The vast majority are, correct?</p> <p>4 A. I mean, I haven't tallied up.</p> <p>5 I don't know percentages, but there are</p> <p>6 articles in there that involve other disease</p> <p>7 states.</p> <p>8 Q. The vast -- would you agree</p> <p>9 that the vast majority of your published</p> <p>10 literature deals with lung disease of one</p> <p>11 kind or another, whether it be transplants,</p> <p>12 cystic fibrosis, COPD, et cetera?</p> <p>13 MS. MILLER: Objection. Asked</p> <p>14 and answered.</p> <p>15 THE WITNESS: I didn't tally it</p> <p>16 up, and I don't have the percentages,</p> <p>17 but I do know that there are many</p> <p>18 articles in there that are written</p> <p>19 about diseases that may not involve</p> <p>20 the lungs.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. I don't think you have to tally</p> <p>23 them up to look at them and see that the vast</p> <p>24 majority of them deal with lung diseases,</p> <p>25 true?</p>	<p>1 A. I don't specifically recall,</p> <p>2 but in this First Aid for Internal Medicine</p> <p>3 Boards there may have been -- there may have</p> <p>4 been some -- some cancer topics in there.</p> <p>5 Q. Do any deal with the</p> <p>6 methodology for assessing causation?</p> <p>7 A. Book chapters on the</p> <p>8 methodology assessing causation? Not that</p> <p>9 I'm aware of.</p> <p>10 Q. Any deal with talcum powder or</p> <p>11 ovarian cancer?</p> <p>12 A. You know, other than the</p> <p>13 potential for there being talk about</p> <p>14 malignancies or cancer in First Aid for</p> <p>15 Internal Medicine Boards, which I don't</p> <p>16 specifically recall.</p> <p>17 Q. Do you think that that</p> <p>18 references talcum powder?</p> <p>19 A. Do I think that what references</p> <p>20 talcum powder?</p> <p>21 Q. That first chapter.</p> <p>22 A. Which one? I'm --</p> <p>23 MS. MILLER: Objection.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. The one you just mentioned.</p>

14 (Pages 50 to 53)

Christian Merlo, M.D., MPH

Page 54	Page 56
<p>1 Do any of your book chapters 2 deal in any way with talcum powder? 3 A. No, they don't. 4 Q. Okay. Prior to finalizing your 5 report in February of 2019, two months ago, 6 had you ever publicly expressed your opinion 7 about talcum powder and ovarian cancer? 8 A. No. 9 Q. Now, we talked about the fact 10 that you were an associate professor at Johns 11 Hopkins critical care. 12 You've been associate professor 13 for how many years? 14 A. I'd have to look back at my CV. 15 It looks like I was promoted to associate 16 professor in 2015. 17 Q. So you've been associate 18 professor for four years? 19 A. That's correct. 20 (Merlo Exhibit 4 marked for 21 identification.) 22 QUESTIONS BY MR. TISI: 23 Q. Okay. I want to show you 24 Exhibit Number 4, which is the -- your bio on 25 your web page for the critical care division</p>	<p>1 Q. Any mention of cancer of any 2 kind? 3 A. There is not. 4 Q. Okay. Now, your CV also 5 mentions that you currently run the adult 6 clinic for a cystic fibrosis center for the 7 past four years, since 2015? 8 A. So I'm the associate program 9 director for our adult cystic fibrosis 10 program at Johns Hopkins. 11 Q. I'm sorry, I promoted you. 12 A. Thank you. It's very difficult 13 to get promoted at Hopkins, so -- 14 Q. Maybe someday. 15 You've held that position since 16 2015? 17 A. Where are you referring -- 18 where are we looking now? 19 Q. Page 2. 20 A. Page 2. 21 Q. I'm sorry, the first page. 22 A. First page. 23 Q. It says, "2015 to present, 24 associate program director, Adult Cystic 25 Fibrosis Center."</p>
Page 55	Page 57
<p>1 of Hopkins. 2 That's your picture, correct? 3 A. That is my picture. 4 Q. Does it list your expertise as 5 cystic fibrosis, lung transplant, pulmonary 6 and critical care medicine? 7 A. Are you referring to up top -- 8 Q. Yes. 9 A. -- to the right? 10 Expertise: cystic fibrosis, 11 lung transplant, pulmonary and critical care 12 medicine -- 13 Q. Yes. 14 A. -- pulmonary? 15 Q. Yeah. 16 A. That's what it says. 17 Q. Does it also say your research 18 interests are HIV-related pulmonary disease, 19 outcomes after lung transplantation, clinics 20 and -- clinical cystic fibrosis? 21 A. That's what it says. 22 Q. Okay. Any mention of ovarian 23 cancer? 24 A. There is no mention of ovarian 25 cancer.</p>	<p>1 A. 2015, yes, that's correct. 2 Q. So for four years you've been 3 an associate professor. For four years 4 you've been an associate program director for 5 the Cystic Fibrosis Clinic. 6 What is cystic fibrosis? 7 A. Cystic fibrosis is a genetic 8 disease that -- some people are born with it, 9 and it leads to an abnormal chloride channel 10 in epithelial-lined cells -- in 11 epithelial-lined organs in the body. In the 12 lungs it leads to a buildup of secretions and 13 progressive lung disease that oftentimes 14 leads to death or lung transplantation. 15 It leads to sinus disease. It 16 leads to liver disease. It leads to problems 17 in the gastrointestinal tract. It leads to 18 infertility in men. It leads to women 19 oftentimes having difficulties getting 20 pregnant. 21 And, unfortunately, there is no 22 cure for it. 23 Q. Is it cancer? 24 A. No. 25 (Merlo Exhibit 5 marked for</p>

15 (Pages 54 to 57)

Christian Merlo, M.D., MPH

Page 58	Page 60
<p>1 identification.)</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. If I could show you</p> <p>4 Exhibit Number 5, which is the web page from</p> <p>5 the Adult Clinic for the Cystic Fibrosis</p> <p>6 Center.</p> <p>7 A. I look much younger there.</p> <p>8 Q. We all look younger, Doctor, at</p> <p>9 different times.</p> <p>10 This is your web page from the</p> <p>11 Johns Hopkins Adult Clinic for Cystic</p> <p>12 Fibrosis?</p> <p>13 A. It's a web page from Hopkins.</p> <p>14 I don't know whose web page it is. I didn't</p> <p>15 make it.</p> <p>16 Q. And it lists you and it -- an</p> <p>17 associate professor of medicine and</p> <p>18 epidemiology, correct? Right under your</p> <p>19 name?</p> <p>20 A. Where are you referring to?</p> <p>21 Q. Right under your name.</p> <p>22 A. I see.</p> <p>23 Associate professor of medicine</p> <p>24 and epidemiology, yes.</p> <p>25 Q. And I will talk about the</p>	<p>1 THE WITNESS: On this website,</p> <p>2 it's listed that my clinical interests</p> <p>3 are cystic fibrosis and lung</p> <p>4 transplantation.</p> <p>5 But again, I have no idea who</p> <p>6 put this together. I don't know if</p> <p>7 they were my colleagues or they're --</p> <p>8 some random person at Hopkins did</p> <p>9 this.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. Did you ever ask to take</p> <p>12 it down?</p> <p>13 A. No.</p> <p>14 Q. Okay. Would you ever tell</p> <p>15 somebody, "let's put in my clinical interests</p> <p>16 here treatment of ovarian cancer"?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: You know, there</p> <p>19 are lots of websites out there, and if</p> <p>20 I spent my time just looking at</p> <p>21 websites, I wouldn't be able to get</p> <p>22 anything done.</p> <p>23 So Hopkins has a lot of web</p> <p>24 presence, and we oftentimes don't know</p> <p>25 what goes up there.</p>
Page 59	Page 61
<p>1 epidemiology portion of it, but right now let</p> <p>2 me ask you this: The research interests</p> <p>3 listed here are outcomes of adults with</p> <p>4 cystic fibrosis infected with multiple</p> <p>5 antibiotic-resistant pneumonias -- and I</p> <p>6 don't even know how to pronounce that last</p> <p>7 word.</p> <p>8 Could you tell me?</p> <p>9 A. Pseudomonas aeruginosa.</p> <p>10 Q. Okay. Diagnosis of management</p> <p>11 of pulmonary arterial venous malformations,</p> <p>12 correct?</p> <p>13 A. I do see that.</p> <p>14 Q. Are there areas of your</p> <p>15 research interests?</p> <p>16 A. Those are things that I've been</p> <p>17 interested in in research, among other</p> <p>18 things. I don't know who put this together</p> <p>19 or where they got those things, so -- but</p> <p>20 that's part of my research interests, sure.</p> <p>21 Q. Your clinical interests, at</p> <p>22 least as described by your colleagues at</p> <p>23 Johns Hopkins, are cystic fibrosis and lung</p> <p>24 transplantation, correct?</p> <p>25 MS. MILLER: Objection.</p>	<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'll just start: Now that</p> <p>3 you've seen it, would you go back to your</p> <p>4 colleagues and say, "You know something, I'm</p> <p>5 an expert in ovarian cancer; you need to list</p> <p>6 that"?</p> <p>7 MS. MILLER: Objection.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: No.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay.</p> <p>12 A. Not on a website.</p> <p>13 Q. Now let's talk a bit about your</p> <p>14 appointment as associate professor of</p> <p>15 medicine and epidemiology at the Johns</p> <p>16 Hopkins School of Public Health.</p> <p>17 You held that position as well,</p> <p>18 right?</p> <p>19 A. Can you say that one more time?</p> <p>20 Q. Yeah.</p> <p>21 Do you hold -- are you -- have</p> <p>22 you been appointed as associate professor of</p> <p>23 medicine and epidemiology at the Johns</p> <p>24 Hopkins School of Public Health?</p> <p>25 A. So I'm appointed an associate</p>

16 (Pages 58 to 61)

Christian Merlo, M.D., MPH

Page 62	Page 64
<p>1 professor of epidemiology at the Johns 2 Hopkins Bloomberg School of Public Health. 3 Q. Now, would you agree that your 4 primary appointment, in terms of the time you 5 spend, is in the pulmonary and critical care 6 area as opposed to the School of Public 7 Health? 8 MS. MILLER: Objection. 9 THE WITNESS: So it depends. 10 It depends on the time of year. It 11 depends on year to year. There may be 12 more -- there may be some years where 13 I spend much more time over at the 14 School of Public Health in 15 collaborating with the epidemiologists 16 over there. There may be years or 17 months where I spend more time in the 18 hospital. There's no way for me to 19 really parse it out. 20 QUESTIONS BY MR. TISI: 21 Q. If you were to -- if you were 22 to -- let's take a year, but we could take 23 four years you've been associate professor. 24 Let's do the big picture first. 25 Over the four years you have</p>	<p>1 for you, this and that. 2 So there's no way for me to 3 parse out whether it's 20/80, 80/20, 4 50/50. It's all related. 5 QUESTIONS BY MR. TISI: 6 Q. Do you have an office over at 7 the School of Public Health? 8 A. I don't have a physical space 9 over at the School of Public Health. 10 Q. Okay. 11 A. I do have -- I do have lab 12 meetings that are located over at the School 13 of Public Health or in other epidemiologic 14 areas that are outside the School of 15 Medicine. 16 Q. Now, there are professors and 17 assistant professors who work only in the 18 Bloomberg School of Public Health, correct? 19 A. There are faculty that are only 20 appointed -- their only appointment is within 21 the School of Public Health, that is correct. 22 Q. And they spend all their 23 professional time in that school -- in the 24 School of Public Health? 25 A. Not necessarily.</p>
Page 63	Page 65
<p>1 been at Hopkins, and you had to give me an 2 estimate of the time you spend over at the 3 Bloomberg School of Public Health as opposed 4 to at the pulmonary and critical care 5 medicine or the cystic fibrosis clinic, 6 basically the Bloomberg School of Public 7 Health and everything else, how would you 8 divide the time over the past four years? 9 MR. LOCKE: Objection. 10 THE WITNESS: I think it's 11 impossible to divide it because I may 12 go to clinic on, say, Wednesday -- 13 Thursday and see transplant patients 14 and see cystic fibrosis patients, but 15 then Friday I'll spend working on a 16 research project with one of my 17 fellows where we have some of the 18 epidemiologists and analysts helping 19 us with our analysis and study 20 designs. 21 There may be times when I'm 22 seeing a patient in clinic, and then I 23 call one of my colleagues over at the 24 School of Public Health because I'm 25 going to say I'm going to get a sample</p>	<p>1 Q. Okay. 2 A. Because Hopkins is a very 3 collaborative place, and even though a 4 faculty member may not have a primary 5 appointment within a school, that doesn't 6 necessarily mean that that person would spend 7 his or her time only in one specific 8 building. 9 Q. Now -- 10 A. It's a very fluid place. 11 Q. Okay. But there are full 12 professors at the Bloomberg School of Public 13 Health, correct? 14 A. There are full professors at 15 the Johns Hopkins Bloomberg School of Public 16 Health. 17 Q. And there are full associate 18 professors at -- full-time associate 19 professors at the Bloomberg School of Public 20 Health? 21 A. There are full-time associate 22 professors at the Bloomberg School of Public 23 Health. 24 (Merlo Exhibit 6 marked for 25 identification.)</p>

17 (Pages 62 to 65)

Christian Merlo, M.D., MPH

Page 66	Page 68
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm going to provide you as</p> <p>3 Exhibit Number 6 the faculty directory at the</p> <p>4 Bloomberg School of -- the epidemiology</p> <p>5 department at the Bloomberg School of Public</p> <p>6 Health.</p> <p>7 MS. MILLER: Are you providing</p> <p>8 it to the rest of us or just to him?</p> <p>9 MR. TISI: I apologize,</p> <p>10 Counsel. I didn't do it quick enough</p> <p>11 for you.</p> <p>12 MS. MILLER: Thank you.</p> <p>13 MR. TISI: Actually, may I have</p> <p>14 one copy back?</p> <p>15 MS. MILLER: Totally.</p> <p>16 MR. TISI: Thank you.</p> <p>17 MS. MILLER: Susan and I can</p> <p>18 share.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. I'll represent to you, Doctor,</p> <p>21 that this is the faculty directory of the</p> <p>22 epidemiology department, Bloomberg School of</p> <p>23 Public Health. It was taken off the website</p> <p>24 before your deposition was moved last week,</p> <p>25 so April 3rd of 2019.</p>	<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. And it's used at Hopkins,</p> <p>3 right?</p> <p>4 A. Dr. Gordis' textbook, when I</p> <p>5 took the course, was used at Hopkins.</p> <p>6 I'm not sure what textbook is</p> <p>7 used for that specific class today.</p> <p>8 Q. And do you know a Dr. -- and I</p> <p>9 can't pronounce his name -- Moyses Szklo?</p> <p>10 A. Yeah, and I -- I'm not sure how</p> <p>11 to pronounce his last -- his last name</p> <p>12 either.</p> <p>13 Q. He's a full professor -- he's a</p> <p>14 full professor of epidemiology, correct?</p> <p>15 A. Moyses Szklo.</p> <p>16 Do I know him? No. I know of</p> <p>17 him.</p> <p>18 Q. Do you know that he took over</p> <p>19 the editing of the book when -- on</p> <p>20 epidemiology when Dr. Gordis passed?</p> <p>21 A. I don't know that.</p> <p>22 Q. Okay. Both of those</p> <p>23 epidemiologists I mentioned, Dr. Szklo and</p> <p>24 Dr. Gordis, were full-time professors at</p> <p>25 the -- or in Dr. Szklo's case still is a</p>
Page 67	Page 69
<p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 MR. LOCKE: Objection.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. And it lists full-time faculty.</p> <p>6 Do you see that?</p> <p>7 A. I don't --</p> <p>8 Q. See on the top -- top right</p> <p>9 here, full time?</p> <p>10 A. I do see that.</p> <p>11 Q. And if you look through here --</p> <p>12 first of all, actually on the front page is a</p> <p>13 gentleman by the name of Leon Gordis.</p> <p>14 Who is Dr. Gordis?</p> <p>15 A. Leon Gordis was an</p> <p>16 epidemiologist who -- when I took</p> <p>17 Epidemiology I at the School of Public</p> <p>18 Health, he taught the course.</p> <p>19 Q. And he is -- he wrote a</p> <p>20 textbook on epidemiology, correct?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I know of a</p> <p>23 textbook that he wrote. He may have</p> <p>24 written multiple, but I know of one.</p> <p>25</p>	<p>1 full-time professor at the Bloomberg School</p> <p>2 of Public Health, correct?</p> <p>3 A. It says right here that he's a</p> <p>4 full-time professor.</p> <p>5 Q. Have you spoke to Dr. Szklo?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: This Dr. Szklo?</p> <p>8 Yeah.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Szklo, is that how you</p> <p>11 pronounce it?</p> <p>12 A. I think so.</p> <p>13 Q. Okay.</p> <p>14 A. I'm not sure. Again, I know of</p> <p>15 him, and I don't think I've ever met him.</p> <p>16 Hopkins is a big place.</p> <p>17 Q. Now, I've -- it's also</p> <p>18 collaborative, right?</p> <p>19 A. It is.</p> <p>20 Q. You told me it's very</p> <p>21 collaborative.</p> <p>22 A. It is. But it's a very big</p> <p>23 place.</p> <p>24 Q. Understood.</p> <p>25 But that's a department that</p>

18 (Pages 66 to 69)

Christian Merlo, M.D., MPH

Page 70	Page 72
<p>1 you've -- I mean, is there anything that</p> <p>2 would prevent you from speaking to Dr. Szklo?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: If I had a reason</p> <p>5 to. But there are many people on here</p> <p>6 that I actually have collaborated</p> <p>7 with, so --</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay.</p> <p>10 A. In particular, Dr. Kirk right</p> <p>11 here, I think he's on many of my articles.</p> <p>12 So, you know, it just depends.</p> <p>13 If there was something specific</p> <p>14 that I thought that we could work on or I had</p> <p>15 a question, I'd just e-mail or call him right</p> <p>16 up and go over there.</p> <p>17 Q. Good to know. We'll talk about</p> <p>18 that.</p> <p>19 (Merlo Exhibit 7 marked for</p> <p>20 identification.)</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. I showed you Exhibit 4, which</p> <p>23 was your personal web page from Johns Hopkins</p> <p>24 pulmonary critical care department.</p> <p>25 Now let me show you the web</p>	<p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. And if you click on that, on</p> <p>4 the computer, you get the second page of this</p> <p>5 document, which is a course catalog.</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. And it says, "No results."</p> <p>9 A. Okay.</p> <p>10 Q. Okay. Do you teach any courses</p> <p>11 in epidemiology?</p> <p>12 A. I do. I teach two.</p> <p>13 Q. Which ones do you teach?</p> <p>14 A. I teach a course called the</p> <p>15 Science of Clinical Investigation and --</p> <p>16 Q. And what is -- I'm sorry.</p> <p>17 A. And that -- and the specific</p> <p>18 aspect of that is the design of clinical</p> <p>19 studies. We have both an in-person class and</p> <p>20 an online course.</p> <p>21 Q. Okay. And is any part of that</p> <p>22 course the discussion of the application of</p> <p>23 the Bradford Hill framework to answering a</p> <p>24 question of causation?</p> <p>25 MS. MILLER: Objection.</p>
Page 71	Page 73
<p>1 page from the Johns Hopkins department of</p> <p>2 epidemiology, which I'd like to have marked</p> <p>3 as Exhibit Number 7.</p> <p>4 Do you see that?</p> <p>5 A. I see a faculty directory for</p> <p>6 Johns Hopkins Bloomberg School of Public</p> <p>7 Health.</p> <p>8 Q. All right. And underneath it</p> <p>9 says, "department affiliation." It says,</p> <p>10 "school of medicine, primary" and</p> <p>11 "epidemiology, joint."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. What does it mean to be</p> <p>15 primary, and what does it mean to be joint?</p> <p>16 A. I actually have no idea. I</p> <p>17 know that my first appointment at Johns</p> <p>18 Hopkins was with the School of Medicine, and</p> <p>19 then because I was teaching courses over at</p> <p>20 the School of Public Health and collaborating</p> <p>21 with some of the investigators over there, we</p> <p>22 talked about another appointment, which I</p> <p>23 guess would be called a joint appointment.</p> <p>24 Q. Okay. It says here, "View</p> <p>25 current courses."</p>	<p>1 THE WITNESS: I don't know that</p> <p>2 I have a specific slide that would say</p> <p>3 Bradford -- there may be. I'd have to</p> <p>4 look back. But we certainly do talk</p> <p>5 about causality.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. And one of the things -- do you</p> <p>8 have slides that you use in that course?</p> <p>9 A. I have slides, and other</p> <p>10 instructors have slides.</p> <p>11 Q. Do you have any objection to</p> <p>12 producing it to us?</p> <p>13 MS. MILLER: I don't think</p> <p>14 that's his decision whether to object</p> <p>15 or not. I think that would be our</p> <p>16 objection.</p> <p>17 MR. TISI: I'm asking whether</p> <p>18 he has any objection.</p> <p>19 MS. MILLER: That's not an</p> <p>20 appropriate question for the witness.</p> <p>21 MR. TISI: I understand.</p> <p>22 Objection.</p> <p>23 MS. MILLER: But if it is</p> <p>24 appropriate or not --</p> <p>25 MR. TISI: Objection.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 74</p> <p>1 Objection.</p> <p>2 MS. MILLER: No, I'm going to</p> <p>3 speak.</p> <p>4 MR. TISI: No, you're not.</p> <p>5 MS. MILLER: You're talking --</p> <p>6 Yes, I am.</p> <p>7 MR. TISI: No, you're not.</p> <p>8 MS. MILLER: Really? You want</p> <p>9 to watch?</p> <p>10 MR. TISI: Let's call the</p> <p>11 judge. Let's go off the record and</p> <p>12 call the judge.</p> <p>13 MS. MILLER: We're going to off</p> <p>14 the record and call the judge and tell</p> <p>15 her that you asked the witness if he</p> <p>16 has any objection to producing a</p> <p>17 document --</p> <p>18 MR. TISI: Yes, does he have</p> <p>19 personal --</p> <p>20 MS. MILLER: -- and won't let</p> <p>21 me talk about the objection. That is</p> <p>22 not an appropriate question.</p> <p>23 MR. TISI: Does he have -- does</p> <p>24 he have any -- do you have any</p> <p>25 objection --</p>	<p style="text-align: right;">Page 76</p> <p>1 talcum powder?</p> <p>2 A. No, although I think it would</p> <p>3 be a very fun exercise during that class.</p> <p>4 Q. Okay. When is the next time</p> <p>5 you give the class?</p> <p>6 A. We give the in-person version</p> <p>7 in the fall, and we give the online version</p> <p>8 usually in the wintertime.</p> <p>9 Q. Have you ever taught strategies</p> <p>10 for investigating the causes of cancer?</p> <p>11 A. Can you ask that again?</p> <p>12 MS. MILLER: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Yes.</p> <p>15 Have you ever taught any</p> <p>16 strategies for investigating the causes of</p> <p>17 cancer?</p> <p>18 MS. MILLER: Same objection.</p> <p>19 THE WITNESS: So I would have</p> <p>20 to say that in certain -- now, for</p> <p>21 instance, in this -- in this</p> <p>22 investigation looking at malignancies</p> <p>23 after a transplant that we did, yeah,</p> <p>24 certainly we talked about aspects of</p> <p>25 how to evaluate the potential</p>
<p style="text-align: right;">Page 75</p> <p>1 MS. MILLER: That is not an</p> <p>2 appropriate question. I'm instructing</p> <p>3 you not to answer.</p> <p>4 THE WITNESS: You can take the</p> <p>5 course.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. I'd love to take the course,</p> <p>8 Doctor.</p> <p>9 A. Great.</p> <p>10 Q. I'd love to learn about the</p> <p>11 levels of evidence. But let's --</p> <p>12 MS. SHARKO: Should we agree?</p> <p>13 MS. MILLER: Yeah.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Let's -- we're going -- on a</p> <p>16 break, we're going to call the judge on that</p> <p>17 question.</p> <p>18 You said you taught a second</p> <p>19 course. What is the second course?</p> <p>20 A. So there's an online version</p> <p>21 and there's an in-person version, and</p> <p>22 sometimes they're a little bit different;</p> <p>23 sometimes they're the same.</p> <p>24 Q. Okay. In any of these courses</p> <p>25 have you ever discussed your opinions on</p>	<p style="text-align: right;">Page 77</p> <p>1 exposure/outcome relationship.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. What article is that, so I can</p> <p>4 look it up?</p> <p>5 A. I'm trying to find the number</p> <p>6 here. 65.</p> <p>7 Q. Thank you.</p> <p>8 What is the title of the</p> <p>9 article? I'm sorry.</p> <p>10 A. "Risk Factors for De Novo</p> <p>11 Malignancy Following Lung Transplantation."</p> <p>12 Q. Okay. Do you know whether or</p> <p>13 not ovarian cancer -- there's an association</p> <p>14 between lung transplantation and ovarian</p> <p>15 cancer?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MS. SHARKO: Could you keep</p> <p>18 your voice up, please, Mr. Tisi?</p> <p>19 MR. TISI: Sure. You know, I'd</p> <p>20 have to -- that's the first time I've</p> <p>21 ever heard you say that.</p> <p>22 MS. SHARKO: I know. I'm --</p> <p>23 MR. TISI: Well, this witness</p> <p>24 is actually pretty good in answering</p> <p>25 questions, so I appreciate that so</p>

20 (Pages 74 to 77)

Christian Merlo, M.D., MPH

Page 78	Page 80
<p>1 far.</p> <p>2 THE WITNESS: I would have to</p> <p>3 specifically look back at that</p> <p>4 article. I don't specifically recall.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Okay. Now, could you go to</p> <p>7 Appendice C of your report? Your report</p> <p>8 which I believe is Exhibit Number 3.</p> <p>9 It's the list of cases that you</p> <p>10 have testified to over the past four years.</p> <p>11 A. Okay.</p> <p>12 Q. And that's exhibit -- and</p> <p>13 that's Exhibit 3 -- and that's Exhibit 3,</p> <p>14 correct?</p> <p>15 A. Yes, correct.</p> <p>16 Q. I want to have -- I believe</p> <p>17 counsel provided us with a supplemental</p> <p>18 exhibit to that. I'll make it 3B because I</p> <p>19 think we have a 3.</p> <p>20 (Merlo Exhibit 3B marked for</p> <p>21 identification.)</p> <p>22 MS. MILLER: You're talking</p> <p>23 about the fact that we didn't know</p> <p>24 what court one of the cases was in or</p> <p>25 something.</p>	<p>1 Q. Okay. Are there times that</p> <p>2 you've consulted on legal cases but not been</p> <p>3 an expert?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Well, being asked</p> <p>6 to consult on a case, I've been</p> <p>7 considered an expert. There have been</p> <p>8 cases that I've turned down because I</p> <p>9 felt like my opinion -- or I felt like</p> <p>10 there wasn't -- there wasn't something</p> <p>11 that I could support or there wasn't</p> <p>12 something that was -- something that I</p> <p>13 could provide an opinion about.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Could you give me an estimate,</p> <p>16 if you would -- I'll talk about your work on</p> <p>17 behalf of Johnson & Johnson in this case, but</p> <p>18 putting that aside for a moment, on the legal</p> <p>19 matters in which you have been either</p> <p>20 identified as an expert or consulted,</p> <p>21 approximately how much have you made the past</p> <p>22 year, money?</p> <p>23 A. Well, first off, I would like</p> <p>24 to clarify that I'm not working on behalf of</p> <p>25 Johnson & Johnson.</p>
Page 79	Page 81
<p>1 MR. TISI: Honestly, I don't</p> <p>2 know. I don't have any idea.</p> <p>3 MS. MILLER: He's talking about</p> <p>4 this.</p> <p>5 MR. TISI: Okay. This is just</p> <p>6 a clerical thing, Doctor.</p> <p>7 Here's -- provided to us. It</p> <p>8 was a supplement. I'm not even going</p> <p>9 to spend any time with it. It's just</p> <p>10 a housekeeping thing.</p> <p>11 MS. MILLER: Yeah, I don't</p> <p>12 think Dr. Merlo was involved in that.</p> <p>13 MR. TISI: Okay.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. So you've given</p> <p>16 testimony in the past four years 20 times?</p> <p>17 A. That seems about -- I mean, I</p> <p>18 don't know if it's exactly 20, but --</p> <p>19 whatever --</p> <p>20 Q. Well, I've counted them up.</p> <p>21 Five times in 2015; three times in 2016; five</p> <p>22 times in 2017, six times in 2018.</p> <p>23 Does that -- does that look</p> <p>24 about right to you?</p> <p>25 A. It looks about right.</p>	<p>1 And I would have to look at my</p> <p>2 tax statement because I don't recall.</p> <p>3 Q. Was it more than \$10,000?</p> <p>4 A. Probably.</p> <p>5 Q. More than 20?</p> <p>6 A. Probably.</p> <p>7 Q. More than 30?</p> <p>8 A. Probably was more than 30.</p> <p>9 Q. More than 40?</p> <p>10 A. Probably.</p> <p>11 Q. More than 50?</p> <p>12 A. Probably.</p> <p>13 Q. More than 60?</p> <p>14 A. In the last year, probably,</p> <p>15 yes.</p> <p>16 Q. More than 70?</p> <p>17 A. Maybe.</p> <p>18 Q. Okay. What about the year</p> <p>19 prior?</p> <p>20 A. I don't recall.</p> <p>21 Q. Okay. The prior -- last year</p> <p>22 you had six times in 2018. 2017 you had five</p> <p>23 times.</p> <p>24 Would it be approximately the</p> <p>25 same?</p>

21 (Pages 78 to 81)

Christian Merlo, M.D., MPH

Page 82	Page 84
<p>1 MS. MILLER: Objection. He 2 said he doesn't remember. 3 MR. TISI: I can -- I can ask 4 these questions. 5 THE WITNESS: Again, I'd 6 probably have to look at my tax 7 records. I'd be just guessing. 8 QUESTIONS BY MR. TISI: 9 Q. Would it be more than 10? 10 A. I'd be guessing. 11 Q. Okay. Over the past four 12 years, have you been provided -- have you 13 provided expert work in litigation fairly 14 consistently? Is that something that you do? 15 MS. MILLER: Objection. 16 THE WITNESS: It's not 17 something I keep track of. I have 18 been -- I have offered opinions as an 19 expert witness, but I don't keep track 20 of how much or how little. 21 QUESTIONS BY MR. TISI: 22 Q. Now in this case, in 2019, have 23 you -- in 2019, have you given any 24 depositions -- we're now in April. Have you 25 been identified as an expert or given any</p>	<p>1 A. I see that, yes. 2 Q. Is that accurate? 3 A. This is an invoice. I haven't 4 seen it yet, but -- 5 Q. Did you do any work for 6 Johnson & Johnson before December of 2018? 7 A. Again, I just would like to 8 clarify. I'm not working for Johnson & 9 Johnson. 10 Q. Okay. Have you been paid by 11 Johnson & Johnson for your time prior to 12 December of 2018? 13 A. Not that I recall. 14 Q. Okay. 15 MS. MILLER: Let us know when 16 it's a good time for a break. 17 QUESTIONS BY MR. TISI: 18 Q. The next document is an invoice 19 showing that you made an additional \$28,995 20 through April 7, 2019; is that correct? 21 MS. MILLER: I'm sorry? 22 THE WITNESS: I'm sorry, could 23 you ask that one more time? 24 MR. TISI: I'm sorry. I'm 25 sorry.</p>
Page 83	Page 85
<p>1 opinions in 2019 other than in this case? 2 A. I'd have to look back through 3 my records. I don't remember. 4 Q. You don't remember giving any 5 depositions or signing any reports over the 6 past three, four months? 7 A. Again, I'd have to look at my 8 records. 9 Q. Okay. In this case we have 10 your records, which I'll mark in a minute. 11 Actually, I'll do it right now. Exhibit 12 Number 8, which are the records of -- 13 provided to us. 14 (Merlo Exhibit 8 marked for 15 identification.) 16 QUESTIONS BY MR. TISI: 17 Q. And it shows that you have made 18 in the Johnson & Johnson litigation about 19 \$150,000 so far this year? 20 A. This looks like a bill or an 21 invoice. 22 Q. One is dated -- one is dated 23 March 1, 2019, and it's -- first date is 24 December 3, 2018, through March 17th, and 25 it's for \$116,000?</p>	<p>1 QUESTIONS BY MR. TISI: 2 Q. It shows just \$5 short of 30 -- 3 \$29,000 as of March 7, 2019? 4 A. That's what the invoice shows, 5 yes. 6 Q. It has a company or LLC here 7 called VeraMedica. 8 What is VeraMedica? 9 A. VeraMedica is an organization. 10 I'm not sure about the -- any of the 11 specifics there, but it's an organization 12 that I used for administrative purposes to 13 put binders together, to make photocopies, to 14 make -- to schedule meetings, those sort of 15 things. 16 Q. Are they a scientific 17 consulting company? 18 A. I have no idea. 19 Q. Do they provide -- did they 20 provide you any support for the reports that 21 you prepare -- the report you prepared in 22 this case? 23 A. Other than making a photocopy 24 or scheduling meetings or helping to give me 25 kind of an office away from an office, that's</p>

22 (Pages 82 to 85)

Christian Merlo, M.D., MPH

Page 86	Page 88
<p>1 the support that they give me.</p> <p>2 Q. And if you give me about five,</p> <p>3 ten minutes, I think we can finish this.</p> <p>4 MR. TISI: Is that okay with</p> <p>5 you, Counsel?</p> <p>6 MS. MILLER: Sure.</p> <p>7 MR. TISI: Okay.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Your expert work you charge</p> <p>10 \$530 an hour, and \$720 an hour for your</p> <p>11 testimony?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. Those are -- those are</p> <p>14 numbers that are -- is there anything built</p> <p>15 into that number?</p> <p>16 We had Dr. Diette the other day</p> <p>17 where a certain portion of his bill went to</p> <p>18 somebody other than himself, so I'm asking</p> <p>19 you that question.</p> <p>20 A. You know, and I'd have -- I</p> <p>21 don't actually know, but I'd have to look</p> <p>22 back or I'd have to talk -- the</p> <p>23 administrative services for -- that were</p> <p>24 supported to me by VeraMedica may be built</p> <p>25 into that.</p>	<p>1 Q. Well, let me show you -- and</p> <p>2 I'm taking this out of order a little bit.</p> <p>3 There's a website that I go to sometimes to</p> <p>4 find this information out.</p> <p>5 It identifies -- and I'm going</p> <p>6 to show you...</p> <p>7 MS. MILLER: We're up to what</p> <p>8 number exhibit?</p> <p>9 MR. TISI: This is 47. It's</p> <p>10 taken out of order because everything</p> <p>11 is marked.</p> <p>12 (Merlo Exhibit 47 marked for</p> <p>13 identification.)</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. It lists payments made by</p> <p>16 pharmaceutical companies to doctors, and I'm</p> <p>17 just curious as to whether this is accurate</p> <p>18 or not.</p> <p>19 Were you paid approximately</p> <p>20 \$44,000 in 2016 --</p> <p>21 MS. MILLER: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. -- by --</p> <p>24 MS. MILLER: Sorry, I thought</p> <p>25 you were done.</p>
Page 87	Page 89
<p>1 MS. MILLER: I would note that</p> <p>2 the -- it says 540 on the --</p> <p>3 MR. TISI: Okay.</p> <p>4 MS. MILLER: -- on here and it</p> <p>5 says 530 on here, so...</p> <p>6 THE WITNESS: And again, I'm</p> <p>7 not sure of the specifics.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay. Now, in addition to</p> <p>10 consulting for litigation purposes like you</p> <p>11 are here, have you also worked directly for</p> <p>12 pharmaceutical companies over the past four,</p> <p>13 five years?</p> <p>14 A. I have not worked directly for</p> <p>15 pharmaceutical companies --</p> <p>16 Q. Well, I'm sorry.</p> <p>17 A. -- over the past four or five</p> <p>18 years.</p> <p>19 Q. That's a bad question.</p> <p>20 Have you been provided funding</p> <p>21 by pharmaceuticals companies like Novartis,</p> <p>22 for example?</p> <p>23 A. So it depends. And that's a</p> <p>24 very general question, so you'd have to be</p> <p>25 very -- even more specific about that.</p>	<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. -- by, among others, Novartis?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: So I'm not really</p> <p>5 sure what this website is.</p> <p>6 I do -- I have been involved in</p> <p>7 think tanks for -- involving other</p> <p>8 doctors and folks to talk about</p> <p>9 aspects of disease, and there have</p> <p>10 been honorariums involved with that.</p> <p>11 I also give speeches to groups,</p> <p>12 mainly groups of doctors and nurses</p> <p>13 and teams that take care of patients</p> <p>14 with cystic fibrosis. And those</p> <p>15 speeches are sometimes sponsored by</p> <p>16 pharmaceutical companies, so -- and</p> <p>17 I'm provided an honorarium to give</p> <p>18 that.</p> <p>19 So this doesn't surprise me.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. So -- and that's what</p> <p>22 I'm trying to get at here, Doctor.</p> <p>23 You can call them honorarium.</p> <p>24 You can call them whatever you want. You</p> <p>25 get -- you get a check from the</p>

Christian Merlo, M.D., MPH

Page 90	Page 92
<p>1 pharmaceutical companies for outside -- work 2 outside of your official duties at Johns 3 Hopkins. 4 And this goes from 2013 to 5 2016, correct? 6 MR. LOCKE: Objection. 7 THE WITNESS: And I am going to 8 say that they're honorarium because 9 that's what they're called. 10 QUESTIONS BY MR. TISI: 11 Q. Okay. 12 A. And I'm asked by sometimes 13 other centers to come, and that -- and 14 that -- to give a speech or a talk to the 15 group, and that talk or speech might be 16 sponsored by a pharmaceutical industry, and 17 that's what this reflects. 18 Q. Okay. And so without getting 19 down to the minutiae, this has 44,000, 20 approximately, in 2016, 31,000 in 2015, 21 79,000 in 2014, and 42,000, approximately, 22 more or less, in 2013. 23 Is that about -- is that 24 accurate or in that ballpark? 25 A. I mean, I'd have to look</p>	<p>1 a group that's taking care of patients with 2 advanced lung disease due to cystic fibrosis. 3 And most times the talks are a 4 description about the disease, either to 5 educate the teams or describe how the process 6 of when a kid grows up to be an adult with 7 cystic fibrosis, how do you take care of the 8 transition process. 9 Most of them don't involve a 10 specific therapy for cystic fibrosis. 11 Oftentimes specific therapies are talked 12 about after the talk with the group, but most 13 times it's done for education purposes. 14 Q. But most of the companies that 15 pay these honorariums actually do produce 16 products used to treat cystic fibrosis and 17 pulmonary disease, correct? 18 A. Which companies are you 19 referring to? 20 Q. Gilead, Novartis. 21 A. Gilead, Novartis do have -- 22 well, Novartis not anymore, but -- 23 Q. They did at the time? 24 A. -- Gilead and Novartis did have 25 products that were used to treat patients</p>
Page 91	Page 93
<p>1 through my records, but that's what the 2 website says. 3 Q. Okay. And is that money that 4 you get as an honorarium yours? 5 A. It is mine, yes. 6 Q. And did you do it in 2017, 7 2018, and continue into 2019? 8 MS. MILLER: Objection. Vague. 9 THE WITNESS: I'd have to look 10 through my records. I have done -- 11 I've given much less talks in the last 12 few years. 13 QUESTIONS BY MR. TISI: 14 Q. And on all the products that 15 you speak about or all the companies that 16 you -- they -- would it be fair to say that 17 they are all focused in the pulmonary area; 18 in other words, either involved treatments 19 for pulmonary disease or descriptions of 20 pulmonary disease? Correct? 21 A. So there's a lot to that 22 question because you mentioned products, you 23 mentioned descriptions, and I probably should 24 break it down a little bit. 25 The talks are usually given to</p>	<p>1 with cystic fibrosis. 2 Q. Okay. So just to wrap this up, 3 and I -- we'll move on to the next topic and 4 take our break. 5 MS. MILLER: Take our break. 6 QUESTIONS BY MR. TISI: 7 Q. You have done work in 8 litigation, which we've talked about earlier, 9 and you did speeches and talks for which you 10 received honorarium from pharmaceutical 11 companies. 12 Do you also -- have you also 13 provided consulting services to 14 pharmaceutical companies or the like that are 15 not giving speeches and all that? 16 A. I mean, I've helped design some 17 of these talks, put together the slides for 18 them, and I have been provided honorariums 19 for that as well. 20 MR. TISI: Let's take our 21 break. 22 VIDEOGRAPHER: The time is 23 10:23 a.m., and we're going off the 24 record. 25 (Off the record at 10:23 a.m.)</p>

24 (Pages 90 to 93)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 94</p> <p>1 VIDEOGRAPHER: The time is</p> <p>2 10:42 a.m., and we are back on the</p> <p>3 record.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Just a couple of questions real</p> <p>6 briefly before I move on to your report.</p> <p>7 You received your master's in</p> <p>8 public health from Johns Hopkins School of</p> <p>9 Public Health in 2003?</p> <p>10 A. Yes, I believe so.</p> <p>11 Q. And who was your advisor?</p> <p>12 A. My advisor in the School of</p> <p>13 Public Health, or the School of Medicine at</p> <p>14 that time?</p> <p>15 Q. School of Public Health.</p> <p>16 A. I believe my advisor may have</p> <p>17 been Marie Diener Smith, but I don't</p> <p>18 specifically recall.</p> <p>19 Q. Did you do a Capstone?</p> <p>20 A. At the time the Capstone</p> <p>21 project was not part of the master's in</p> <p>22 public health.</p> <p>23 Q. Okay. Did you have to do any</p> <p>24 kind of final project to get your MPH?</p> <p>25 A. We had a final project</p>	<p style="text-align: right;">Page 96</p> <p>1 A. I don't know specifically. I</p> <p>2 don't know if advisors are assigned or</p> <p>3 advisors are recommended and then the student</p> <p>4 decides. I just don't know.</p> <p>5 Q. Have you ever had a student who</p> <p>6 did a Capstone project with you that was not</p> <p>7 pulmonary in nature?</p> <p>8 A. I've had students who have</p> <p>9 worked with me that have been outside of</p> <p>10 pulmonary and critical care medicine.</p> <p>11 Q. Okay.</p> <p>12 A. Two have been surgeons who have</p> <p>13 worked on -- that we wound up working on many</p> <p>14 projects together.</p> <p>15 Q. Okay. All right. So when was</p> <p>16 the first time you met with -- who was your</p> <p>17 primary contact for the ovarian cancer report</p> <p>18 that we've marked as Exhibit 3? Which of the</p> <p>19 lawyers?</p> <p>20 Who first contacted you for</p> <p>21 this project?</p> <p>22 A. Ms. Miller.</p> <p>23 Q. Okay. And when was that done?</p> <p>24 When was the first contact you had with</p> <p>25 Ms. Miller?</p>
<p style="text-align: right;">Page 95</p> <p>1 assignment with Biostatistics IV where we had</p> <p>2 to design a clinical study, do the analysis</p> <p>3 and write up a manuscript, which was</p> <p>4 eventually published, but that was my final</p> <p>5 project.</p> <p>6 Q. And was it a pulmonary study?</p> <p>7 A. It was a study looking at risk</p> <p>8 factors for resistant organisms in cystic</p> <p>9 fibrosis.</p> <p>10 Q. Okay. So it was a pulmonary</p> <p>11 cystic fibrosis study?</p> <p>12 A. It was a cystic fibrosis study.</p> <p>13 Q. Okay.</p> <p>14 A. An epidemiologic cystic</p> <p>15 fibrosis study.</p> <p>16 Q. Are you a Capstone advisor for</p> <p>17 any students in the School of Public Health?</p> <p>18 A. I have been in the past. I'm</p> <p>19 not this year.</p> <p>20 Q. Okay. How does the School of</p> <p>21 Public Health assign students to advisors for</p> <p>22 their Capstone project?</p> <p>23 I mean, do they look at</p> <p>24 qualifications, et cetera, areas of interest,</p> <p>25 research?</p>	<p style="text-align: right;">Page 97</p> <p>1 A. 2018.</p> <p>2 Q. Okay. When?</p> <p>3 A. Late 2018. I don't</p> <p>4 specifically recall.</p> <p>5 Q. The first billing record that</p> <p>6 we had when we looked at that exhibit, I</p> <p>7 think Exhibit 8, had a December 2018 date.</p> <p>8 Is that about right?</p> <p>9 A. It would have been before that.</p> <p>10 Q. Okay. Was December 2018 the</p> <p>11 first actual work you did on the project?</p> <p>12 A. What do you mean by "work"?</p> <p>13 Q. It's the first time you billed,</p> <p>14 so why would that be the -- I mean, did you</p> <p>15 do work for which you did not bill?</p> <p>16 A. It -- just if you could be a</p> <p>17 little bit more specific about what you mean</p> <p>18 by "work."</p> <p>19 Q. I can't go by anything any --</p> <p>20 for more than what you billed.</p> <p>21 How long between the first</p> <p>22 contact and the first work you did on the</p> <p>23 case that would start the process of</p> <p>24 resulting in the report that was issued in</p> <p>25 February?</p>

Christian Merlo, M.D., MPH

Page 98	Page 100
<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I don't</p> <p>3 specifically recall.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Okay.</p> <p>6 MS. MILLER: Don't forget to</p> <p>7 give me ten seconds before you answer.</p> <p>8 THE WITNESS: I'm sorry.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Prior to -- now, we had</p> <p>11 indicated that you did some litigation work.</p> <p>12 You did some consulting work for which you</p> <p>13 received honoraria.</p> <p>14 Had you ever worked -- had you</p> <p>15 ever had -- done litigation work for</p> <p>16 Johnson & Johnson previously?</p> <p>17 A. Well, again, I'd have to</p> <p>18 clarify. I'm not doing litigation work for</p> <p>19 Johnson & Johnson.</p> <p>20 Q. How would you -- so we don't</p> <p>21 have to dance around that issue, how would</p> <p>22 you --</p> <p>23 A. But you keep asking it, so --</p> <p>24 MR. LOCKE: Objection.</p> <p>25</p>	<p>1 me, right?</p> <p>2 So you're being paid by the</p> <p>3 folks sitting next to you, and where it comes</p> <p>4 from, we'll leave that -- we'll leave that to</p> <p>5 other people to decide.</p> <p>6 The question is: You are being</p> <p>7 paid to be here today?</p> <p>8 A. I will submit a bill, and I</p> <p>9 will be paid for being here today.</p> <p>10 Q. Have you ever had any similar</p> <p>11 circumstances in cases involving Johnson &</p> <p>12 Johnson before?</p> <p>13 A. I don't believe that I have --</p> <p>14 I don't believe so.</p> <p>15 Q. Okay. Has Johnson & Johnson,</p> <p>16 putting litigation aside, ever hired you or</p> <p>17 paid you honoraria to actually speak on a</p> <p>18 topic?</p> <p>19 A. I've never been paid an</p> <p>20 honorarium or have been hired by Johnson &</p> <p>21 Johnson.</p> <p>22 Q. Okay. Have they ever consulted</p> <p>23 you in any way for any scientific reason</p> <p>24 outside of litigation?</p> <p>25 A. Johnson & Johnson has not</p>
Page 99	Page 101
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, okay. So you tell me --</p> <p>3 you tell me how I would phrase it so we don't</p> <p>4 have to keep going back and forth on that.</p> <p>5 MS. MILLER: Objection.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. What makes you more</p> <p>8 comfortable?</p> <p>9 Have you ever done consulting</p> <p>10 work for Johnson & Johnson in a litigation</p> <p>11 context before?</p> <p>12 A. Again, the premise there is</p> <p>13 that I'm doing something for someone, and I'm</p> <p>14 not doing something for anyone.</p> <p>15 Q. Are you being paid by them?</p> <p>16 A. I don't know who I'm being paid</p> <p>17 by.</p> <p>18 Q. You don't know who -- you don't</p> <p>19 know that the lawyers here are paying you for</p> <p>20 your time here today?</p> <p>21 A. Again, I don't know who is</p> <p>22 paying me. I know I'm getting paid, but I</p> <p>23 don't know who is paying me.</p> <p>24 Q. Okay. You're being paid in</p> <p>25 this litigation. You're not being paid by</p>	<p>1 consulted me outside of this litigation.</p> <p>2 Q. Now, Merlo -- you know that</p> <p>3 this report was filed in the context of</p> <p>4 litigation, correct, Exhibit 3? It's got a</p> <p>5 legal caption on it.</p> <p>6 A. Exhibit 3, yes.</p> <p>7 Q. Okay. And it was requested as</p> <p>8 a result -- it was -- I'm sorry, it was</p> <p>9 generated as a result of a request from the</p> <p>10 lawyers for J&J?</p> <p>11 A. I was asked -- I'll just read</p> <p>12 this right here. I was asked to address</p> <p>13 fundamental tenets of epidemiology, to review</p> <p>14 epidemiology related to the potential</p> <p>15 association between perineal talc use and</p> <p>16 ovarian cancer, to review plaintiffs'</p> <p>17 epidemiologic expert reports, and to offer my</p> <p>18 opinions on their methodologies.</p> <p>19 Q. Who asked you to do that?</p> <p>20 A. I was asked by Ms. Miller.</p> <p>21 Q. Okay. And when you drafted --</p> <p>22 when you did that, you understood that your</p> <p>23 report was being submitted in the context of</p> <p>24 this litigation, correct?</p> <p>25 A. I understood that I would put</p>

26 (Pages 98 to 101)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 102</p> <p>1 together a report and that would likely be 2 submitted. 3 Q. In litigation? 4 A. In litigation. 5 Q. Okay. So this report that you 6 have in front of you, Exhibit Number 6, was 7 not generated in your normal course of your 8 professional work as a professor or -- excuse 9 me, as an assistant professor at Johns 10 Hopkins, either in the School of Public 11 Health or the department of medicine? 12 MS. MILLER: Objection. 13 THE WITNESS: Can you ask that 14 again? 15 QUESTIONS BY MR. TISI: 16 Q. Yes. 17 So the report that you have in 18 front of you, Exhibit Number 3, was 19 generated -- was not generated in the normal 20 course of your professional work as a 21 professor or researcher at either the School 22 of Medicine or the School of Public Health at 23 Johns Hopkins? 24 MS. MILLER: Objection. 25 THE WITNESS: So I'd say it</p>	<p style="text-align: right;">Page 104</p> <p>1 THE WITNESS: Can you ask that 2 again? 3 QUESTIONS BY MR. TISI: 4 Q. Yes. 5 Would you have done this report 6 had Ms. Miller not asked you to do it? 7 A. I would not have specifically 8 put this together. 9 Q. Okay. 10 A. Had not been asked to provide 11 my opinions on this topic. 12 Q. Right. 13 And before Ms. Miller reached 14 out to you in December of 2018, some five 15 months ago, you had never expressed an 16 opinion one way or another about the risk of 17 ovarian cancer associated with talcum powder 18 products, have you? 19 MR. LOCKE: Objection. 20 MS. MILLER: Objection. 21 THE WITNESS: Can you ask that 22 one more time? 23 QUESTIONS BY MR. TISI: 24 Q. Yes. 25 A. I'm sorry, I'm just getting --</p>
<p style="text-align: right;">Page 103</p> <p>1 depends. Because if we look at it as 2 a report in itself and how I approach 3 this subject, that would be very 4 similar to how I approach a lot of 5 things in my -- in my career. So -- 6 and in my professional duties within 7 the School of Medicine and 8 epidemiology. 9 So is this any different? No. 10 QUESTIONS BY MR. TISI: 11 Q. I didn't ask you that question, 12 Doctor. With all due respect, I think you 13 need to listen to my question. 14 My question is: Was this 15 particular report on talcum powder product 16 and ovarian cancer done in connection with 17 your duties and responsibilities at Johns 18 Hopkins? 19 MS. MILLER: That wasn't your 20 question. 21 MR. LOCKE: Objection. 22 MS. MILLER: That's a different 23 question. I just want to make that 24 clear. And I'm objecting to this 25 question as well.</p>	<p style="text-align: right;">Page 105</p> <p>1 when I hear objections, I just -- 2 Q. Yeah, they're intended to be 3 that way. 4 A. No, but it's -- so I need to 5 think about the question. 6 MS. MILLER: They're not 7 intended to be that way. That was not 8 a necessary comment. 9 QUESTIONS BY MR. TISI: 10 Q. Let me ask you this question. 11 Before your report in February, 12 Exhibit Number 3, had you ever expressed the 13 opinion on page 46 of your report that says, 14 "When analyzed in a methodologic manner, the 15 body of medical literature simply does not 16 support the conclusion that perineal exposure 17 to talc causes ovarian cancer"? 18 Have you ever said that 19 statement or any statement similar to that 20 prior to your report being filed on 21 February 25, 2019? 22 A. I had not said that prior to 23 this because I had not reviewed all of this 24 literature prior to that. 25 Q. Okay. So all the literature</p>

27 (Pages 102 to 105)

Christian Merlo, M.D., MPH

Page 106	Page 108
<p>1 review that you did in this case was as a</p> <p>2 result of being retained in this case?</p> <p>3 A. The literature review that I</p> <p>4 did in this case was because I was asked to</p> <p>5 provide an opinion on that.</p> <p>6 Q. Prior to Ms. Miller contacting</p> <p>7 you, had you ever read any of the articles</p> <p>8 that you read in connection with this report</p> <p>9 on talc and ovarian cancer?</p> <p>10 A. Likely no.</p> <p>11 Q. Okay. Now, you mentioned, if</p> <p>12 you go to page 1 of your report, the scope of</p> <p>13 your report -- as I count it, you have -- you</p> <p>14 did three things.</p> <p>15 You were asked to address</p> <p>16 fundamental tenets of epidemiology, correct?</p> <p>17 A. Address fundamental tenets of</p> <p>18 epidemiology.</p> <p>19 Q. Okay. Number 2, review the</p> <p>20 epidemiology of the potential association</p> <p>21 between perineal talc use and ovarian cancer,</p> <p>22 correct?</p> <p>23 A. To review the epidemiology</p> <p>24 related to the potential association between</p> <p>25 perineal talc use and ovarian cancer,</p>	<p>1 MS. MILLER: I think if you let</p> <p>2 him finish --</p> <p>3 MR. TISI: I said I'm</p> <p>4 withdrawing the question. Okay?</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. I assume that you have reviewed</p> <p>7 fundamental tenets of epidemiology prior to</p> <p>8 December of 2018?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I have reviewed</p> <p>11 and I teach fundamental tenets of</p> <p>12 epidemiology.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. Putting that aside,</p> <p>15 prior to December of 2018, have you ever</p> <p>16 reviewed the epidemiology related to the</p> <p>17 potential exposure between perineal talc use</p> <p>18 and ovarian cancer?</p> <p>19 A. The potential exposure?</p> <p>20 Q. Association.</p> <p>21 A. I had not reviewed epidemiology</p> <p>22 related to the potential association between</p> <p>23 perineal talc and ovarian cancer.</p> <p>24 Q. Before December of 2018?</p> <p>25 A. Specifically, it may have been</p>
Page 107	Page 109
<p>1 correct.</p> <p>2 Q. And the third assignment was to</p> <p>3 review plaintiffs' epidemiology reports and</p> <p>4 offer your opinion on their methodologies?</p> <p>5 A. So those are two different</p> <p>6 things. To review plaintiffs' epidemiology</p> <p>7 expert reports and then to offer my opinions</p> <p>8 on their methodologies would be a separate</p> <p>9 thing.</p> <p>10 Q. Okay. All right. And to be</p> <p>11 clear, the scope -- the things that you did</p> <p>12 for this report as indicated on page 1, the</p> <p>13 four items we've talked about, are things you</p> <p>14 never did before December of 2019 {sic}?</p> <p>15 MS. MILLER: Objection.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. 2018?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: Well, not</p> <p>20 necessarily.</p> <p>21 I think if we --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Actually, let me rephrase the</p> <p>24 question.</p> <p>25 You have --</p>	<p>1 November. I don't remember when we first</p> <p>2 talked, but --</p> <p>3 Q. Let's say the last quarter.</p> <p>4 A. -- late 2018.</p> <p>5 Q. Okay. So within the past eight</p> <p>6 or nine months?</p> <p>7 A. Before late 2018? No, I did --</p> <p>8 had not reviewed the epidemiology --</p> <p>9 Q. Okay.</p> <p>10 A. -- related to the potential</p> <p>11 association between perineal talc exposure</p> <p>12 and ovarian cancer.</p> <p>13 Q. Okay. And if you go to</p> <p>14 page 46 -- and we touched on this. You said</p> <p>15 your opinion on Issue Number 2, which would</p> <p>16 be the results of your analysis of the</p> <p>17 epidemiology related to the potential</p> <p>18 association between perineal use and ovarian</p> <p>19 cancer, your opinion was: When analyzed in a</p> <p>20 methodologic manner, the body of medical</p> <p>21 literature simply does not support the</p> <p>22 conclusion that perineal talc exposure causes</p> <p>23 ovarian cancer.</p> <p>24 A. And we're referring to page 46</p> <p>25 of --</p>

28 (Pages 106 to 109)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 110</p> <p>1 Q. Correct.</p> <p>2 A. -- this report?</p> <p>3 And which line was that?</p> <p>4 Q. The last paragraph.</p> <p>5 A. "When analyzed in a</p> <p>6 methodologic manner, the body of medical</p> <p>7 literature simply does not support the</p> <p>8 conclusion that perineal exposure to talc</p> <p>9 causes ovarian cancer," yes.</p> <p>10 (Merlo Exhibit 9 marked for</p> <p>11 identification.)</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. And I have that conclusion</p> <p>14 marked as Exhibit Number 9. Read it and tell</p> <p>15 me if it's correct.</p> <p>16 A. That's correct.</p> <p>17 Q. And that's your professional</p> <p>18 opinion on the issue of causation, correct?</p> <p>19 A. That is my professional and</p> <p>20 epidemiologic opinion on causation.</p> <p>21 Q. Okay.</p> <p>22 A. Correct.</p> <p>23 Q. Did you -- in addition to</p> <p>24 providing basic epidemiologic principles, did</p> <p>25 you apply your professional and epidemiologic</p>	<p style="text-align: right;">Page 112</p> <p>1 a group of epidemiology studies mean, true?</p> <p>2 A. Can you say that again?</p> <p>3 Q. Yeah.</p> <p>4 Oftentimes experts in</p> <p>5 epidemiology disagree about what an</p> <p>6 epidemiology study actually means or a group</p> <p>7 of epidemiology studies actually means?</p> <p>8 A. There may be instances where</p> <p>9 epidemiologists may disagree on methodologies</p> <p>10 and how a study was performed.</p> <p>11 The interpretation of results</p> <p>12 is usually something that is not disagreed</p> <p>13 upon. It's usually the methodology that</p> <p>14 leads to the disagreement.</p> <p>15 Q. Well, for an individual study,</p> <p>16 the results are what the results are, true?</p> <p>17 A. For an individual study, the</p> <p>18 results are usually what the results are</p> <p>19 based on -- but those are -- with the caveat</p> <p>20 that there are a lot of aspects that go into</p> <p>21 those results: the study design, the study</p> <p>22 type, whether or not bias and confounding was</p> <p>23 accounted for before or after the analysis,</p> <p>24 was the analysis appropriate.</p> <p>25 So those results can't just be</p>
<p style="text-align: right;">Page 111</p> <p>1 judgment to answer that question?</p> <p>2 A. I don't know what you mean by</p> <p>3 "epidemiologic judgment."</p> <p>4 Q. Well, this -- epidemiology</p> <p>5 isn't the kind science where you just plug</p> <p>6 numbers in and you come out with an answer,</p> <p>7 right?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: Well,</p> <p>10 epidemiology can be very objective and</p> <p>11 not subjective, and oftentimes there</p> <p>12 are numbers involved in epidemiology.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Clearly there are numbers --</p> <p>15 clearly there are numbers involved.</p> <p>16 But an expert in epidemiology</p> <p>17 also has to use their professional judgment</p> <p>18 interpreting the numbers, correct?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: I don't know what</p> <p>21 you mean by "interpreting the</p> <p>22 numbers."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Well, oftentimes experts</p> <p>25 disagree about what an epidemiology study or</p>	<p style="text-align: right;">Page 113</p> <p>1 taken out of context without looking at all</p> <p>2 the other aspects of the study.</p> <p>3 Q. Okay. And when -- now, putting</p> <p>4 aside looking at the results of an individual</p> <p>5 study, when you're looking at a body of</p> <p>6 literature, all right, multiple epidemiology</p> <p>7 studies, multiple biologic studies, and</p> <p>8 trying to interpret a body of literature, do</p> <p>9 you use professional judgment?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Again, I don't --</p> <p>12 I don't know what "professional</p> <p>13 judgment" means. I don't understand</p> <p>14 what you mean by that, so --</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you know if that's a phrase</p> <p>17 that's used in textbooks that are used at</p> <p>18 Johns Hopkins, that you teach students?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: I mean, I have no</p> <p>21 idea. There's lots of textbooks. You</p> <p>22 would have to point me to one that</p> <p>23 you're referring to.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. We will do that.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 114</p> <p>1 Now, apart from your own</p> <p>2 causation opinion, which we've marked as</p> <p>3 Exhibit Number 9, I think, right there -- is</p> <p>4 that number 9?</p> <p>5 A. That's number 9.</p> <p>6 Q. You also, as part of your</p> <p>7 assignment, offered opinions on the</p> <p>8 plaintiffs' experts' reports, true?</p> <p>9 A. That's correct.</p> <p>10 Q. Okay. And in fact, if you go</p> <p>11 to page 46 of your report, you devoted the</p> <p>12 vast majority of your conclusion paragraphs</p> <p>13 to discussing the methodologies that are used</p> <p>14 by plaintiffs' experts in reaching their</p> <p>15 conclusions.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. For example, you say in</p> <p>19 paragraph 2, "The methodologies used by</p> <p>20 plaintiffs' experts ignore fundamental</p> <p>21 principles of epidemiology. In particular,</p> <p>22 plaintiffs' experts ignore the hierarchy of</p> <p>23 evidence evaluating studies and rely on study</p> <p>24 designs that are inherently susceptible to</p> <p>25 bias. Specifically plaintiffs' experts pay</p>	<p style="text-align: right;">Page 116</p> <p>1 THE WITNESS: So in --</p> <p>2 MS. MILLER: Ten seconds.</p> <p>3 THE WITNESS: So in general,</p> <p>4 the hierarchy of evidence does put</p> <p>5 certain study designs above others.</p> <p>6 Meta-analyses are usually put above</p> <p>7 randomized controlled trials.</p> <p>8 Randomized controlled trials are</p> <p>9 usually put above cohort studies.</p> <p>10 Cohort studies are usually put above</p> <p>11 case-control studies. Case-control</p> <p>12 studies are usually put above case</p> <p>13 series or cross-sectional studies.</p> <p>14 But it depends. It depends on</p> <p>15 many, many -- it depends on many, many</p> <p>16 factors, and you can't just take that</p> <p>17 in itself.</p> <p>18 A poorly designed randomized</p> <p>19 controlled trial may be much less</p> <p>20 informative than a very, very good</p> <p>21 cohort study.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. Then you say -- a</p> <p>24 separate criticism. You say, "Plaintiffs'</p> <p>25 experts generally agree that even if the</p>
<p style="text-align: right;">Page 115</p> <p>1 particular attention to criticizing cohort</p> <p>2 studies, with little acknowledgement to the</p> <p>3 limitations of case-control studies that find</p> <p>4 weak associations."</p> <p>5 Did I read that correctly?</p> <p>6 A. That's correct.</p> <p>7 Q. Okay. So you think that there</p> <p>8 is a hierarchy of evidence that is generally</p> <p>9 accepted?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: It's not what I</p> <p>12 think. There is a general hierarchy</p> <p>13 of evidence --</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay.</p> <p>16 A. -- in the epidemiologic</p> <p>17 community --</p> <p>18 Q. Okay.</p> <p>19 A. -- and so there are different</p> <p>20 levels of evidence based on a study design.</p> <p>21 Q. Okay. And on that -- under</p> <p>22 that design hierarchy, cohort studies are</p> <p>23 more reliable than case-control studies, as a</p> <p>24 general matter?</p> <p>25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 117</p> <p>1 studies do show an association between talc</p> <p>2 use and ovarian cancer, have found a relative</p> <p>3 risk in the range of 1.2 to 1.6, this, by</p> <p>4 definition, is a weak association."</p> <p>5 Do you see that?</p> <p>6 A. I do, yes.</p> <p>7 Q. Okay. And you're critical of</p> <p>8 their description of the strength of the</p> <p>9 association?</p> <p>10 A. Relative risk in the range of</p> <p>11 1.2 to 1.6 is, by definition, a weak</p> <p>12 association.</p> <p>13 Q. Whose definition?</p> <p>14 A. I think I have a reference in</p> <p>15 here.</p> <p>16 Q. Yeah, you have a reference to</p> <p>17 an Australian white paper.</p> <p>18 A. And in the epidemiology --</p> <p>19 epidemiologic community, a relative risk or</p> <p>20 an odds ratio of less than 2 would be</p> <p>21 considered a weak association --</p> <p>22 Q. Okay.</p> <p>23 A. -- and very, very easy --</p> <p>24 easily -- with the susceptibility to be</p> <p>25 easily explained away by bias or confounding,</p>

30 (Pages 114 to 117)

Christian Merlo, M.D., MPH

Page 118	Page 120
<p>1 and that's why it's considered a weak 2 association. 3 Q. The next thing you say is, 4 "Likewise, plaintiffs' experts demonstrate a 5 dose-response relationship in relying on 6 methodologically flawed studies and 7 statistically insignificant trend lines." 8 A. That's correct. 9 Q. Okay. And then another thing 10 is you say, "They see consistency where the 11 studies are inherently inconsistent." 12 A. That's correct. 13 Q. Okay. So those are the four 14 main criticisms that you have? 15 MS. MILLER: Objection. 16 THE WITNESS: That's what it 17 says here, yeah. 18 (Merlo Exhibit 10 marked for 19 identification.) 20 QUESTIONS BY MR. TISI: 21 Q. Okay. So I have pulled 22 together -- so it will help us frame our 23 discussion today, I pulled those four, put 24 them on a slide, and I'm going to ask you to 25 look at it and tell me whether you agree that</p>	<p>1 explain on the record my objections to 2 this exhibit. 3 MR. TISI: Objection to form is 4 the question {sic}. 5 MS. MILLER: That's -- you 6 can't object to the form of an 7 exhibit. 8 MR. TISI: Fine. Objection. 9 MS. MILLER: Excuse me. Please 10 let me finish -- 11 MR. TISI: Objection. 12 MS. MILLER: -- my sentence. 13 You're being really rude to me. 14 MR. TISI: I'm being -- you 15 know, honestly, you have been so 16 unprofessional with every one of these 17 witnesses, and I have today pulled 18 together all of your objections over 19 the past couple of depositions, I've 20 put them on a spreadsheet, and I will 21 send them to judge -- to Judge Pisano 22 and have him look at whether or not 23 your objections comply with the CMO. 24 MS. SHARKO: Calm down. 25 MR. TISI: Okay. So if we're</p>
Page 119	Page 121
<p>1 those -- I'm sorry. Can I have that one 2 back? That's my copy. 3 MS. MILLER: Yeah. 4 I'm going to object to this 5 exhibit. I think this pulls four 6 sentences out of a 46-page report. It 7 says "Merlo allegations," and Merlo's 8 not making allegations. He's -- 9 MR. TISI: Oh, he's making 10 plenty of allegations, and your 11 expert -- 12 MS. SHARKO: Don't interrupt. 13 MS. MILLER: Excuse me. 14 MR. TISI: I'm going to tell 15 you the -- Jessica, we're not going to 16 get into this. You've been -- 17 MS. MILLER: I'm going to 18 object to this exhibit -- 19 MR. TISI: So just say 20 "objection." 21 MS. MILLER: -- and I'm going 22 to explain -- no. 23 MR. TISI: No. You're not 24 going to. Objection. 25 MS. MILLER: I'm going to</p>	<p>1 going to -- if we're going to go down 2 this today as we did in the Shih 3 deposition, the Ballman deposition and 4 every other deposition in this case, 5 I'm going to pull them, I'm going to 6 send them to Judge Pisano, and we're 7 going to have a hearing. 8 MS. MILLER: I'm not going to 9 be intimidated by your threats. 10 MR. TISI: So let's just -- 11 let's just comply with the CMO and say 12 "objection." 13 MS. MILLER: This is an 14 inappropriate exhibit. 15 MR. TISI: Fine. Objection. 16 MR. LOCKE: I object as well. 17 QUESTIONS BY MR. TISI: 18 Q. Doctor, are those four 19 criticisms -- 20 MS. MILLER: Excuse me. Do you 21 have something to say? 22 MR. LOCKE: Yeah, I object as 23 well for the same bases. 24 MR. TISI: Okay. 25 MR. LOCKE: It doesn't even</p>

31 (Pages 118 to 121)

Christian Merlo, M.D., MPH

Page 122	Page 124
<p>1 quote --</p> <p>2 MR. TISI: Tom --</p> <p>3 MR. LOCKE: -- what's there.</p> <p>4 MR. TISI: Tom, I'm asking</p> <p>5 him -- I haven't asked a question yet.</p> <p>6 MS. MILLER: It doesn't matter</p> <p>7 whether you've asked the question.</p> <p>8 We're objecting to the exhibit itself.</p> <p>9 MR. TISI: Fine.</p> <p>10 MS. MILLER: It's an</p> <p>11 inappropriate exhibit.</p> <p>12 MR. TISI: So just say</p> <p>13 objection.</p> <p>14 MS. SHARKO: I don't think we</p> <p>15 have to do that. If you're concerned</p> <p>16 about the witness hearing what we're</p> <p>17 saying, he can leave the room.</p> <p>18 MR. TISI: I'm happy to leave</p> <p>19 the room --</p> <p>20 MS. SHARKO: This is totally</p> <p>21 inappropriate, Mr. Tisi, and you know</p> <p>22 it.</p> <p>23 MR. TISI: I can provide him</p> <p>24 with a plate of spaghetti and ask him</p> <p>25 questions about it if I want to.</p>	<p>1 MR. LOCKE: Objection.</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I don't know what</p> <p>4 you mean by "serious charges."</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Well, you say that each of</p> <p>7 plaintiffs' experts used Bradford Hill in a</p> <p>8 manner that was irregular and suggest</p> <p>9 results-driven approach.</p> <p>10 Do you remember that?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Where are you</p> <p>13 referring to?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Well, go to page 40, if you</p> <p>16 could, of your report.</p> <p>17 On your report, you use the</p> <p>18 phrase that "they jumped to causation without</p> <p>19 sufficiently determining association."</p> <p>20 That's a word you use. That's</p> <p>21 the -- that's Section C.</p> <p>22 Do you see that?</p> <p>23 A. It says, "Jumping to causation</p> <p>24 without sufficiently determining</p> <p>25 association."</p>
Page 123	Page 125
<p>1 Okay? It's not inappropriate.</p> <p>2 MR. LOCKE: And it would be a</p> <p>3 complete waste of time.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Doctor, let me ask you: Are</p> <p>6 these four criticisms that are on that</p> <p>7 exhibit criticisms that you have of</p> <p>8 plaintiffs' experts?</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 MR. TISI: Can I have the</p> <p>12 spreadsheet that you made copies of</p> <p>13 today? Because I'm going to mark that</p> <p>14 as an exhibit.</p> <p>15 THE WITNESS: I didn't say</p> <p>16 these things.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay. So you disagree.</p> <p>19 Is there anything that I would</p> <p>20 need to make those things -- to make them</p> <p>21 accurate?</p> <p>22 A. It's all in my report.</p> <p>23 Q. Okay. So let's do this. You</p> <p>24 make serious charges against plaintiffs'</p> <p>25 experts in your report, do you not?</p>	<p>1 Q. Okay. So they jumped to</p> <p>2 causation.</p> <p>3 Is that a word that you used or</p> <p>4 is it a word that was provided to you by</p> <p>5 defense lawyers in this case?</p> <p>6 MS. MILLER: Objection.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: Again, I didn't</p> <p>9 say "they." It just says, "C, jumping</p> <p>10 to causation without sufficiently</p> <p>11 determining association."</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. And then you describe what the</p> <p>14 plaintiffs' experts allegedly did, correct?</p> <p>15 A. It's all -- it's all in my</p> <p>16 report.</p> <p>17 Q. Okay. And on page 35 of your</p> <p>18 report, you say that they "ignored and</p> <p>19 disregarded well-established hierarchy."</p> <p>20 A. Which page? I'm sorry.</p> <p>21 Q. Page 35.</p> <p>22 And this is under the title of</p> <p>23 Methodologic Flaws in Plaintiffs' Experts'</p> <p>24 Epidemiology-Based Opinions, correct?</p> <p>25 A. Where are you referring to?</p>

32 (Pages 122 to 125)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 126</p> <p>1 Q. Right there.</p> <p>2 A. I know, but what -- I see that,</p> <p>3 Methodologic Flaws in Plaintiffs' Experts.</p> <p>4 Q. Right.</p> <p>5 And Section A is, "disregard</p> <p>6 for the hierarchy of evidence."</p> <p>7 A. Section A does say "disregard</p> <p>8 for the hierarchy of evidence."</p> <p>9 Q. And the third paragraph starts</p> <p>10 with, "A number of plaintiffs'</p> <p>11 epidemiologists ignore well-established</p> <p>12 hierarchy of evidence," correct?</p> <p>13 A. In my report it says, "A number</p> <p>14 of plaintiffs' epidemiologists ignore the</p> <p>15 well-established hierarchy of evidence."</p> <p>16 Q. And under the section that says</p> <p>17 Methodologic Flaws of Plaintiffs' Experts'</p> <p>18 Epidemiology-Based Opinions, you also say</p> <p>19 that they "fabricated consistency by ignoring</p> <p>20 studies that did not support their</p> <p>21 conclusion" on page 44, correct?</p> <p>22 A. And where is that on page 44?</p> <p>23 Q. Well, Section 2 says,</p> <p>24 "Plaintiffs' experts fabricate consistency by</p> <p>25 ignoring inconsistent studies."</p>	<p style="text-align: right;">Page 128</p> <p>1 fabrication?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: It says,</p> <p>4 "Plaintiffs' experts fabricate</p> <p>5 consistency by ignoring inconsistent</p> <p>6 studies."</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. And that is a pretty serious</p> <p>9 thing to say about another scientist, is it</p> <p>10 not?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Not if it's not</p> <p>13 true.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. And so your opinion is</p> <p>16 that these experts fabricated opinions?</p> <p>17 A. What this is saying is that</p> <p>18 plaintiffs' expert fabricate consistency, not</p> <p>19 fabricating an opinion; fabricate consistency</p> <p>20 when consistency does not exist.</p> <p>21 Q. Well, one of their opinions is</p> <p>22 that there is consistency, correct?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: There is</p> <p>25 opinions -- well, you'd have to show</p>
<p style="text-align: right;">Page 127</p> <p>1 A. It says Section 2, "Plaintiffs'</p> <p>2 experts fabricate consistency by ignoring</p> <p>3 inconsistent studies."</p> <p>4 Q. That is a very -- to charge</p> <p>5 another scientist with fabrication is a</p> <p>6 pretty serious charge, is it not?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. It's not one that scientists</p> <p>11 make lightly, is it?</p> <p>12 A. I'm not fabri -- I'm not -- I'm</p> <p>13 not charging anyone with anything.</p> <p>14 Q. Well, you're saying that that's</p> <p>15 what they did, correct?</p> <p>16 You're saying that "plaintiffs'</p> <p>17 experts fabricated consistency by ignoring</p> <p>18 inconsistent results."</p> <p>19 A. The studies were inconsistent.</p> <p>20 Q. Okay.</p> <p>21 A. So to say that they're</p> <p>22 consistent is --</p> <p>23 Q. A fabrication?</p> <p>24 A. -- inconsistent.</p> <p>25 Q. And you're saying that's a</p>	<p style="text-align: right;">Page 129</p> <p>1 me who you're talking about and --</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Well, you wrote this, Doctor.</p> <p>4 You wrote this, Doctor. You wrote this,</p> <p>5 Doctor. Okay?</p> <p>6 You said that "plaintiffs'</p> <p>7 experts fabricate consistency by ignoring</p> <p>8 inconsistent studies."</p> <p>9 That was your words, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. All right. Now, my question to</p> <p>12 you is: You are -- you know that plaintiffs'</p> <p>13 experts, using your words here, said that the</p> <p>14 studies were consistent.</p> <p>15 A. We'd have to go through each</p> <p>16 expert and look --</p> <p>17 Q. You've done that before today,</p> <p>18 right?</p> <p>19 A. But we'd have to do it today.</p> <p>20 Q. You've done that in preparation</p> <p>21 of this report?</p> <p>22 A. I've read all the reports.</p> <p>23 Q. Okay. And so you wouldn't say</p> <p>24 that "plaintiffs' experts fabricated</p> <p>25 consistency by ignoring inconsistent results"</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 130</p> <p>1 had you not actually done the work to make</p> <p>2 that conclusion, correct?</p> <p>3 A. I have read the expert --</p> <p>4 Q. Okay.</p> <p>5 A. -- reports, but for the purpose</p> <p>6 of today, we would have to --</p> <p>7 Q. I'm going to ask you that. I'm</p> <p>8 going to ask you that, Doctor.</p> <p>9 My question is: That's a</p> <p>10 pretty serious thing for one scientist to say</p> <p>11 about another.</p> <p>12 MS. MILLER: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. How would you -- how would you</p> <p>15 react if somebody said you -- that you</p> <p>16 fabricated your opinion in this case?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: I didn't say that</p> <p>19 there's fabrication of opinion. I</p> <p>20 said that's fabricating consistency,</p> <p>21 and that's a very different thing.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. And you don't think that</p> <p>24 the experts in this case testified that they</p> <p>25 thought the studies were consistent?</p>	<p style="text-align: right;">Page 132</p> <p>1 medical evidence and the literature, there's</p> <p>2 tremendous inconsistency between study</p> <p>3 designs, cohort studies and case controls,</p> <p>4 and even within study designs.</p> <p>5 Q. Okay. And then --</p> <p>6 A. In looking at the difference</p> <p>7 between hospital-based case controls and</p> <p>8 population-based controls, there's</p> <p>9 inconsistency.</p> <p>10 Q. Okay. And we're going to talk</p> <p>11 about that. Okay. I promise you we're going</p> <p>12 to talk about that.</p> <p>13 But the question is: When you</p> <p>14 use a word like "fabrication," you would</p> <p>15 agree that that is a word that is -- has a</p> <p>16 particular understanding in science as being</p> <p>17 a very bad thing?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I would neither</p> <p>20 agree nor disagree with that. I don't</p> <p>21 know even what you mean by "that's a</p> <p>22 very bad thing."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. So if somebody said to you,</p> <p>25 "Doctor, your report contains fabricated</p>
<p style="text-align: right;">Page 131</p> <p>1 A. We'd have to look at each</p> <p>2 expert and go through. It's a very general</p> <p>3 question.</p> <p>4 Q. So you didn't do that before</p> <p>5 today?</p> <p>6 MS. MILLER: Objection.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. You actually cite Moorman's</p> <p>9 report, Siemiatycki's report, Singh's report,</p> <p>10 McTiernan's report. You cited all these --</p> <p>11 all these here. And we can go through them,</p> <p>12 and I'm happy to go through them.</p> <p>13 But I'm asking you about your</p> <p>14 report. And this report says that it is --</p> <p>15 that it is your review -- they said it was</p> <p>16 consistent; you said that was fabricated.</p> <p>17 Right?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: What I say is,</p> <p>20 "plaintiffs' experts fabricate</p> <p>21 consistency by ignoring inconsistent</p> <p>22 studies."</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay.</p> <p>25 A. And when we look at the body of</p>	<p style="text-align: right;">Page 133</p> <p>1 conclusions or fabricated methodologies,"</p> <p>2 would you not take that seriously?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: I don't know what</p> <p>5 a fabricated conclusion is or a</p> <p>6 fabricated methodology, sir.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. You don't know what that is.</p> <p>9 But you used the word -- what</p> <p>10 did you mean by "fabrication"? The word</p> <p>11 "fabrication."</p> <p>12 What does the word</p> <p>13 "fabrication" mean to you?</p> <p>14 A. What I mean is plaintiffs'</p> <p>15 experts are making a case for consistency</p> <p>16 when consistency does not exist.</p> <p>17 Q. Okay. Well, you go on to say,</p> <p>18 Doctor, at the very last page, you say -- or</p> <p>19 the paragraph says, "As a professor of</p> <p>20 medicine and public health, I have focused my</p> <p>21 career using science of epidemiology as a</p> <p>22 scientific tool to help improve the</p> <p>23 understanding of health and disease. The</p> <p>24 distortion of epidemiologic science for</p> <p>25 purposes of litigation does not achieve those</p>

34 (Pages 130 to 133)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 134</p> <p>1 goals; instead, it undermines scientific</p> <p>2 efforts to better understand the etiology of</p> <p>3 disease."</p> <p>4 Is it your opinion that</p> <p>5 plaintiffs' experts distorted the</p> <p>6 epidemiologic science for purposes of</p> <p>7 litigation?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: That's what I</p> <p>10 wrote in my report.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Did you mean to refer to</p> <p>13 plaintiffs' experts here?</p> <p>14 A. In any epidemiologic study --</p> <p>15 Q. I'm asking you this question.</p> <p>16 MS. MILLER: Please let him</p> <p>17 answer.</p> <p>18 THE WITNESS: In any</p> <p>19 epidemiologic study, if science is</p> <p>20 distorted for the purpose of</p> <p>21 litigation, it goes against --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Right.</p> <p>24 A. -- what I've done in my --</p> <p>25 Q. And you're claiming that's what</p>	<p style="text-align: right;">Page 136</p> <p>1 disease."</p> <p>2 Q. Right.</p> <p>3 A. "The distortion of</p> <p>4 epidemiologic science for purposes of</p> <p>5 litigation does not achieve this goal."</p> <p>6 Q. Okay.</p> <p>7 A. "Instead, it undermines</p> <p>8 scientific efforts to better understand the</p> <p>9 etiology of disease."</p> <p>10 Q. We read that. Now I'm asking</p> <p>11 you a question about that.</p> <p>12 My question is: Is it your</p> <p>13 opinion that that's what the plaintiffs'</p> <p>14 experts did in this case?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I don't know what</p> <p>17 the experts did in this case as far as</p> <p>18 with regards to that.</p> <p>19 What I can say is that the</p> <p>20 distortion of epidemiologic science</p> <p>21 for purposes of litigation does not</p> <p>22 achieve those goals.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay. I'm asking you this</p> <p>25 question. You have to answer this question.</p>
<p style="text-align: right;">Page 135</p> <p>1 defendants -- that that's what plaintiffs'</p> <p>2 experts did in this case.</p> <p>3 A. Can you say that again?</p> <p>4 Q. Yes.</p> <p>5 You say you don't do that,</p> <p>6 right?</p> <p>7 You don't distort the</p> <p>8 scientific evidence for the purposes of</p> <p>9 litigation, right?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Can you ask that</p> <p>12 question --</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Yes.</p> <p>15 A. -- just a little slower?</p> <p>16 You're speaking very fast.</p> <p>17 Q. You say that -- you say, as a</p> <p>18 professor of medicine in public health, it's</p> <p>19 a bad thing to distort the epidemiologic</p> <p>20 evidence for litigation, true?</p> <p>21 A. What I say is, "As a professor</p> <p>22 of medicine in public health, I have focused</p> <p>23 my career on using the science of</p> <p>24 epidemiology as a scientific tool to help</p> <p>25 improve our understanding of health and</p>	<p style="text-align: right;">Page 137</p> <p>1 Okay?</p> <p>2 Is it your opinion, to a</p> <p>3 reasonable degree of medical and scientific</p> <p>4 certainty, that plaintiffs' experts distorted</p> <p>5 the epidemiologic science for the purposes of</p> <p>6 litigation?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: So I believe I</p> <p>9 answered that already.</p> <p>10 I -- the methodology that was</p> <p>11 performed by plaintiffs' experts is</p> <p>12 flawed, and, therefore, my opinions in</p> <p>13 relation to the potential causal</p> <p>14 association between talcum powder and</p> <p>15 ovarian cancer -- when I think of --</p> <p>16 when I -- based on the body of medical</p> <p>17 evidence, there is no causal</p> <p>18 association between perineal talc</p> <p>19 usage and ovarian cancer.</p> <p>20 And the critique I have against</p> <p>21 plaintiffs' opinions relate to their</p> <p>22 methodology.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Right.</p> <p>25 And is it your opinion -- I</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 138</p> <p>1 understand you have a difference of opinion</p> <p>2 on their methodology. But you take it one</p> <p>3 step further, right?</p> <p>4 You say it was their</p> <p>5 methodology -- at least the implication is,</p> <p>6 and I'm asking you the question: Are you</p> <p>7 suggesting that they fabricated in a</p> <p>8 methodology for the purposes of litigation?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. MILLER: Objection. Asked,</p> <p>11 answered, mischaracterizes his</p> <p>12 opinions and his testimony.</p> <p>13 THE WITNESS: I believe I</p> <p>14 answered that.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Okay. I want to hear about</p> <p>17 your litigation -- I want to hear about what</p> <p>18 your opinion is as the motivation for doing</p> <p>19 what they did.</p> <p>20 Is it your opinion that their</p> <p>21 motive in drafting their reports and using</p> <p>22 the methodology that they use was to assist</p> <p>23 in litigation?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: I have no idea</p>	<p style="text-align: right;">Page 140</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. So you have no idea what the</p> <p>3 motive and intent of plaintiffs' experts were</p> <p>4 in drafting their opinions, right?</p> <p>5 A. I have no idea.</p> <p>6 Q. Okay. Are you saying that the</p> <p>7 methodology that they used was fraudulent?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: I don't think</p> <p>10 that there's -- are you referring to</p> <p>11 any part of my report that says</p> <p>12 fraudulent?</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. I'm asking you your opinion --</p> <p>15 I'm asking your opinion right now, under</p> <p>16 oath.</p> <p>17 Are you saying that the</p> <p>18 opinions that they offered was fraudulent?</p> <p>19 MS. MILLER: Objection.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. The methodology they used was</p> <p>22 fraudulent?</p> <p>23 A. Probably have to be a little</p> <p>24 bit more specific.</p> <p>25 Q. Tell me what your views are on</p>
<p style="text-align: right;">Page 139</p> <p>1 what their motivation was.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. So then why is it in here? Why</p> <p>4 is anything about litigation even in your</p> <p>5 report, Doctor?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: Because if</p> <p>9 epidemiologic science is distorted for</p> <p>10 the purposes of litigation, it does</p> <p>11 not achieve those goals.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. And do you think that that's</p> <p>14 what they did?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I have no idea</p> <p>17 what they did.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Okay. So you'd take that out</p> <p>20 of this report?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: My report is my</p> <p>24 report. It stands.</p> <p>25</p>	<p style="text-align: right;">Page 141</p> <p>1 that.</p> <p>2 A. Which expert are we talking</p> <p>3 about? Which part of the methodology?</p> <p>4 Which --</p> <p>5 Q. Okay. Do you think that</p> <p>6 Dr. Siemiatycki applied a fraud -- a</p> <p>7 professor of epidemiology applied -- who has</p> <p>8 sat on IARC and looked at cancer and exposure</p> <p>9 to disease applied a fraudulent methodology?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: No. I don't even</p> <p>13 know what a fraudulent methodology is.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. Do you think he applied</p> <p>16 a litigation or results-driven methodology?</p> <p>17 A. I don't -- I don't know what a</p> <p>18 litigation -- I don't know what a litigation</p> <p>19 methodology would be.</p> <p>20 Q. Well, it says -- do you believe</p> <p>21 that he distorted the epidemiologic</p> <p>22 sciences -- science for the purpose of</p> <p>23 litigation?</p> <p>24 A. I never said that</p> <p>25 Dr. Siemiatycki distorted epidemiologic</p>

36 (Pages 138 to 141)

Christian Merlo, M.D., MPH

Page 142	Page 144
<p>1 science.</p> <p>2 Q. Okay. Do you think that</p> <p>3 Dr. McTiernan did?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Can you ask that</p> <p>6 one more time?</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Yes.</p> <p>9 Do you think that Dr. McTiernan</p> <p>10 distorted epidemiologic science?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: I have no idea.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. Do you think that</p> <p>15 Dr. Smith-Bindman distorted science?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: I don't know.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Do you think that Dr. Singh</p> <p>20 distorted science?</p> <p>21 A. The same answer stands.</p> <p>22 Q. Dr. Moorman, do you think she</p> <p>23 distorted science?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: I think -- I</p>	<p>1 shaking --</p> <p>2 MR. TISI: Okay. That's fine.</p> <p>3 MS. SHARKO: -- and I ask that</p> <p>4 you calm down.</p> <p>5 MR. TISI: I think it's -- I</p> <p>6 think -- you can ask if I'd calm down,</p> <p>7 but when this gentleman comes in here</p> <p>8 and says our experts fabricated,</p> <p>9 ignored, I take it personally.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I want to hear -- I want to</p> <p>12 ask -- I want to ask you this question,</p> <p>13 Doctor.</p> <p>14 MS. SHARKO: Well, I think</p> <p>15 you're misrepresenting his report, and</p> <p>16 he's told that you.</p> <p>17 MR. TISI: Well, if you are,</p> <p>18 then maybe -- maybe he ought to back</p> <p>19 down on some of the adjectives he</p> <p>20 uses.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. Doctor, do you believe --</p> <p>23 MS. SHARKO: Do you need a</p> <p>24 break, Mr. Tisi?</p> <p>25 MR. TISI: No, I don't, Susan,</p>
Page 143	Page 145
<p>1 can't -- I can't speak to the</p> <p>2 motivations of someone else.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Do you believe that the same</p> <p>5 standards you would apply to plaintiffs'</p> <p>6 experts should apply to your opinions: You</p> <p>7 shouldn't fabricate; you shouldn't distort;</p> <p>8 you shouldn't ignore?</p> <p>9 MS. MILLER: Objection.</p> <p>10 That's --</p> <p>11 MR. TISI: Let the record</p> <p>12 reflect you're once again laughing.</p> <p>13 MS. MILLER: -- four questions.</p> <p>14 MS. SHARKO: I'm smiling.</p> <p>15 MR. TISI: You're laughing.</p> <p>16 MS. SHARKO: No. I think --</p> <p>17 MR. TISI: I don't ask -- I'm</p> <p>18 not asking her anything. The record</p> <p>19 will reflect is you were laughing.</p> <p>20 MS. SHARKO: The record will</p> <p>21 reflect that you are not asking him a</p> <p>22 single question like you're supposed</p> <p>23 to.</p> <p>24 You're barking things. You're</p> <p>25 raising your voice. Your hands are</p>	<p>1 but maybe you do.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Let me ask you this question,</p> <p>4 Doctor.</p> <p>5 Do you believe that the same</p> <p>6 standards that you apply to reviewing</p> <p>7 plaintiffs' experts in this report should</p> <p>8 apply to your report as well?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I believe that my</p> <p>11 opinion is made based on the body of</p> <p>12 medical evidence. And for someone to</p> <p>13 say that there is consistency when</p> <p>14 consistency doesn't exist, or strength</p> <p>15 of association when strength of</p> <p>16 association doesn't exist, or there is</p> <p>17 a dose response when dose response</p> <p>18 doesn't exist, that's ignoring the</p> <p>19 body of evidence.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. And you would take issue</p> <p>22 if you ignored evidence of the strength of</p> <p>23 association, correct?</p> <p>24 MS. MILLER: Objection.</p> <p>25</p>

37 (Pages 142 to 145)

Christian Merlo, M.D., MPH

Page 146	Page 148
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. If you ignored evidence of</p> <p>3 consistency, if you ignored evidence of dose</p> <p>4 response, you would be subject to the same</p> <p>5 criticism. You would hold yourself up to no</p> <p>6 different scrutiny than you would imply --</p> <p>7 you would impose on plaintiffs' experts,</p> <p>8 agreed?</p> <p>9 MS. MILLER: Objection. There</p> <p>10 was a question, and before he could</p> <p>11 answer it, you asked another question.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Would you agree that you should</p> <p>15 not fabricate inconsistency when there is</p> <p>16 consistency?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: If we just go</p> <p>19 back to the medical evidence in this</p> <p>20 specific case, the fact that there is</p> <p>21 no strength of association or --</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. I'm not asking you that</p> <p>24 question. Doctor, I'm going to move to</p> <p>25 strike it. And honestly, we're going to</p>	<p>1 A. I don't know what that means.</p> <p>2 Q. Okay. Do you think you should</p> <p>3 not fabricate a methodology for the purposes</p> <p>4 of litigation?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: I never said</p> <p>7 fabricating methodology.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Okay. Do you think that you</p> <p>10 should not -- you should not ignore evidence</p> <p>11 and well-established principles?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: Can you ask that</p> <p>14 one more time?</p> <p>15 MR. TISI: Yeah.</p> <p>16 THE WITNESS: I'm not sure I</p> <p>17 understood what that --</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Do you think you should not</p> <p>20 ignore evidence?</p> <p>21 Should you ignore evidence?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I mean, in</p> <p>24 looking at the causal association</p> <p>25 between exposure and outcome, we try</p>
Page 147	Page 149
<p>1 need -- we may need to take a break on this</p> <p>2 because you need to listen to my question.</p> <p>3 My question is: Would you hold</p> <p>4 yourself to the same standards that you have</p> <p>5 criticized the plaintiffs' experts for?</p> <p>6 I'm not asking about the</p> <p>7 evidence in this case.</p> <p>8 Scientifically, would you agree</p> <p>9 that you should not -- you should not ignore</p> <p>10 consistency when it exists?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: Can you ask that</p> <p>13 one more time?</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Yes.</p> <p>16 Do you agree that you should</p> <p>17 not fabricate an opinion?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: I don't know what</p> <p>20 that means.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. You don't know -- well, you</p> <p>23 used the word "fabrication." It's your word.</p> <p>24 A. Well, fabricate an opinion.</p> <p>25 Q. Yes.</p>	<p>1 to look at all the evidence.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Do you know Sonal Singh?</p> <p>4 A. No.</p> <p>5 Q. He previously worked at</p> <p>6 Hopkins.</p> <p>7 Did he distort science?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: I have no idea.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. Now, let me see if I</p> <p>12 can...</p> <p>13 As you know, I represent women</p> <p>14 who claim to have developed ovarian cancer as</p> <p>15 a result of using talcum powder products.</p> <p>16 You understand that, correct?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: If you're telling</p> <p>19 me that, that's fine.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. You were first consulted</p> <p>22 in this case in December of 2019 {sic},</p> <p>23 correct?</p> <p>24 MS. MILLER: Objection. Asked</p> <p>25 and answered multiple times.</p>

38 (Pages 146 to 149)

Christian Merlo, M.D., MPH

Page 150	Page 152
<p>1 THE WITNESS: Somewhere around 2 there. I don't remember the specific 3 time. 4 MS. MILLER: Please let me 5 finish my objections. 6 QUESTIONS BY MR. TISI: 7 Q. Prior to being contacted by the 8 lawyers -- 9 MS. SHARKO: I assume you mean 10 December 2018. 11 MR. TISI: 2018. 12 QUESTIONS BY MR. TISI: 13 Q. Prior to being contacted by the 14 lawyers representing Johnson & Johnson to 15 defend them in lawsuits, you had never 16 expressed the causation opinions, any of the 17 information in Exhibit Number 3, correct, 18 other than the general principles of 19 epidemiology? Any -- let me rephrase the 20 question. 21 Prior to December of 2018, you 22 had never expressed opinions about talc and 23 ovarian cancer, true? 24 A. That's about right. 25 Q. Okay. And you do know that the</p>	<p>1 A. There are hospital-based 2 case-control studies. There are 3 population-based case-control studies, pool 4 case-control studies, cohort studies. 5 Q. They go from the 1980s, 1990s, 6 2000s and 2010s. Four decades, correct? 7 A. Spanning 1982 through 2016 for 8 these studies that we're talking about right 9 here. 10 Q. Were you involved in any of 11 these studies in any way even peripherally? 12 A. I was not. 13 Q. Okay. Had anybody in this 14 period of time ever contacted you and said, 15 "You know, we have this issue out there about 16 whether or not talcum powder products are 17 associated with ovarian cancer; could you 18 consult with us on that question?" 19 MS. MILLER: Objection. 20 THE WITNESS: What period of 21 time are we talking about? 22 QUESTIONS BY MR. TISI: 23 Q. 1982 till today. 24 Other than the lawyers. 25 A. Can you ask me that question</p>
Page 151	Page 153
<p>1 epidemiologic -- the first epidemiologic 2 study was published by researchers at Harvard 3 University in 1982, correct? 4 MS. MILLER: Objection. 5 THE WITNESS: I would have to 6 look back through the -- through my 7 report and see where those researchers 8 are from. 9 (Merlo Exhibit 12 marked for 10 identification.) 11 QUESTIONS BY MR. TISI: 12 Q. Well, let me provide you with a 13 copy of an article by Cramer, et al. 14 You've seen this study before, 15 correct? 16 A. Cramer, yes, 1982. 17 Q. Okay. And you were just 18 looking at your chart on page 34 and 35 of 19 the various studies, correct? 20 A. That's correct. 21 Q. Okay. There are over 30 22 studies that you identified here, 23 hospital-based, population-based, 24 case-control studies, pooled case-control 25 studies and cohort studies, correct?</p>	<p>1 again then? 2 Q. Yeah. 3 From 1982 until today, has 4 anybody, other than the lawyers for Johnson & 5 Johnson, ever asked you your opinions about 6 ovarian cancer and talcum powder products? 7 MS. MILLER: Objection. 8 THE WITNESS: Well, I believe I 9 answered that already, because I told 10 you when I was first approached to see 11 if I could offer an opinion. 12 QUESTIONS BY MR. TISI: 13 Q. That's a different question. 14 My question is: Outside of 15 lawyers, outside of lawyers in litigation, 16 has any scientist ever come up to you and 17 said, "Dr. Merlo, you are an epidemiologist 18 and a pulmonary and critical care professor 19 at Johns Hopkins. I'd like you to give me 20 your thoughts on the relationship between 21 ovarian cancer and talcum powder products." 22 MS. MILLER: Objection. 23 THE WITNESS: No one has asked 24 me to give an opinion in that time 25 period from 1982 to 2016.</p>

39 (Pages 150 to 153)

Christian Merlo, M.D., MPH

Page 154	Page 156
<p>1 QUESTIONS BY MR. TISI: 2 Q. Has anyone ever consulted you 3 and said, "What do you think about these 4 studies?" 5 A. No. 6 Q. Has anyone ever said to you, 7 "Doctor, you know, the evidence is really 8 unclear; can you help us design a study?" 9 MS. MILLER: Objection. 10 THE WITNESS: No. 11 QUESTIONS BY MR. TISI: 12 Q. Has anybody ever come to you 13 from Johnson & Johnson and say, "You know, we 14 have these different regulatory bodies 15 looking at the issue, NTP, the National 16 Toxicology Project, IARC, the FDA, Health 17 Canada, looking at this issue; would you come 18 help us explain to these various regulatory 19 bodies what the science is about talc and 20 ovarian cancer?" 21 MS. MILLER: Objection. 22 THE WITNESS: No, but I would 23 have been excited to do it. 24 QUESTIONS BY MR. TISI: 25 Q. You know that Congress just</p>	<p>1 to express your opinions to the United States 2 Congress about the relationship between 3 ovarian cancer and talcum powder products? 4 MS. MILLER: Objection. 5 THE WITNESS: No. No. But 6 again, I would have been excited to do 7 something like that. 8 QUESTIONS BY MR. TISI: 9 Q. Did any scientist at Johnson & 10 Johnson ever come to you and say, "You know, 11 we have" -- you understand Health Canada has 12 reviewed the evidence, correct? 13 A. I don't have -- I don't know 14 anything about Health Canada. 15 Q. Okay. Health Canada, you know, 16 is the Canadian equivalent to the United 17 States FDA? 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 THE WITNESS: I have no idea 21 what Health Canada is. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. And have you ever been 24 asked by the scientists, as opposed to the 25 lawyers at Johnson & Johnson, to express your</p>
Page 155	Page 157
<p>1 held a hearing on the issue of ovarian cancer 2 and talcum powder products, correct? 3 A. I have no idea. 4 Q. You know Dr. McTiernan appeared 5 before -- appeared before the House of 6 Representatives to express her opinions in a 7 public forum, correct? 8 MS. MILLER: Objection. 9 THE WITNESS: Again, I have no 10 idea. 11 QUESTIONS BY MR. TISI: 12 Q. Do you know that -- did Johnson 13 & Johnson ever ask you, "You know, Dr. Merlo, 14 we need somebody to present our point of view 15 on what the science says. Would you go 16 testify before Congress?" 17 Did they tell you that? 18 MS. MILLER: Objection. 19 THE WITNESS: Did they tell me 20 what? 21 QUESTIONS BY MR. TISI: 22 Q. Did they ask you to do that? 23 MS. MILLER: Objection. Vague. 24 QUESTIONS BY MR. TISI: 25 Q. Did Johnson & Johnson ask you</p>	<p>1 opinion before any regulatory or professional 2 body on the relationship between ovarian 3 cancer and talcum powder products? 4 MS. MILLER: Objection. 5 THE WITNESS: No, and I believe 6 I've answered this before, but I would 7 have been -- having reviewed the 8 literature, I would be really excited 9 to do that. 10 QUESTIONS BY MR. TISI: 11 Q. Uh-huh. Let me ask you this, 12 Doctor -- maybe Ms. Sharko will ask you to do 13 it after this deposition. We'll find out. 14 Has Johnson & Johnson ever come 15 to you and asked you, we have -- to do a 16 causation analysis on any issue, on any 17 product it markets? 18 A. They have not. 19 Q. And you know Johnson & 20 Johnson's a big company. They produce -- 21 they produce pharmaceutical drugs. They 22 produce cosmetics. They produce 23 over-the-counter drugs. They produce all 24 kinds of drugs, right? 25 MS. MILLER: Objection.</p>

40 (Pages 154 to 157)

Christian Merlo, M.D., MPH

Page 158	Page 160
<p>1 THE WITNESS: I have no idea.</p> <p>2 I mean, I know of Johnson & Johnson,</p> <p>3 but I don't have an opinion on what</p> <p>4 they do or have really any knowledge</p> <p>5 on what they do.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. And other than the litigation,</p> <p>8 they never came to you to ask your advice on</p> <p>9 anything, true?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: I think we've</p> <p>12 talked about that. They didn't ask me</p> <p>13 to do anything.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Now, in this case, literally</p> <p>16 millions of documents have been produced --</p> <p>17 millions of pages of documents have been</p> <p>18 produced to us.</p> <p>19 Would it surprise you that the</p> <p>20 name Christian Merlo doesn't appear in any of</p> <p>21 them?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I don't know what</p> <p>24 you're referring to.</p> <p>25</p>	<p>1 done on this issue, have you ever either been</p> <p>2 approached or approached Johnson & Johnson</p> <p>3 and said, "You know something, I'm an expert</p> <p>4 in design of studies. Let me help you design</p> <p>5 a study that would -- that would answer this</p> <p>6 question once and for all"?</p> <p>7 MS. MILLER: Objection.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. Has that ever happened?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: Excuse me. That</p> <p>12 has not happened.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay.</p> <p>15 A. However, I would gladly like to</p> <p>16 be involved in something like that.</p> <p>17 Q. Okay.</p> <p>18 A. I think the key issue here in</p> <p>19 designing a clinical study like that is there</p> <p>20 are a lot of difficulties.</p> <p>21 Q. Well, you can't do a clinical</p> <p>22 trial on this issue, can you?</p> <p>23 A. Well, it depends what you mean</p> <p>24 by a clinical trial, because clinical trials</p> <p>25 can be cohort studies; they can be</p>
Page 159	Page 161
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Millions of pages of documents</p> <p>3 relating to research and marketing and</p> <p>4 evidence and -- about ovarian cancer and its</p> <p>5 relationship to talcum powder products, the</p> <p>6 composition of talcum powder, all kinds of</p> <p>7 issues, have been produced to us in this</p> <p>8 case.</p> <p>9 Would it surprise you that your</p> <p>10 name doesn't appear even once over the past</p> <p>11 40 or 50 years of documents that we've</p> <p>12 received?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: No, it wouldn't</p> <p>15 surprise me, but my opinion on this</p> <p>16 and the potential association --</p> <p>17 potential causal association between</p> <p>18 talcum powder and ovarian cancer is</p> <p>19 based on the medical literature.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. Have the scientists at</p> <p>22 Johnson & Johnson ever reached out to you and</p> <p>23 said -- even as of today, even as of the day</p> <p>24 you wrote this report criticizing the various</p> <p>25 studies that have been done in this case,</p>	<p>1 case-control studies.</p> <p>2 Q. Understood.</p> <p>3 You cannot randomize patients</p> <p>4 to receiving talcum powder products, and it</p> <p>5 would be unethical and unfeasible to study</p> <p>6 this question using a randomized, controlled,</p> <p>7 placebo-controlled trial?</p> <p>8 A. It would be very difficult to</p> <p>9 perform a randomized controlled trial.</p> <p>10 Q. It would also be -- it would</p> <p>11 not only be difficult, it would be unethical</p> <p>12 if the hypothesis was to assess whether or</p> <p>13 not talcum powder products cause ovarian</p> <p>14 cancer?</p> <p>15 A. Usually when randomized</p> <p>16 controlled trials are designed, by</p> <p>17 definition, if there is a -- if you're</p> <p>18 testing a hypothesis that something is</p> <p>19 causing something, usually you wouldn't</p> <p>20 perform a randomized controlled trial.</p> <p>21 Q. It would be unethical. There</p> <p>22 are rules against that, correct?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: There are rules</p> <p>25 against randomized controlled trials</p>

41 (Pages 158 to 161)

Christian Merlo, M.D., MPH

Page 162	Page 164
<p>1 when the hypothesis is that you're 2 going to cause -- there is the 3 potential to cause harm. 4 QUESTIONS BY MR. TISI: 5 Q. Right. 6 So it's not -- it's not -- you 7 would not expect to see clinical trials in a 8 setting like this? 9 A. Again, these are -- there are 10 clinical trials that have been done, but we 11 wouldn't expect to see a randomized 12 controlled trial performed here. 13 Q. Okay. And you would agree with 14 me that in circumstances like this, what 15 typically experts have are epidemiology 16 studies, observational studies. 17 MS. MILLER: Can you just ask 18 that again? 19 QUESTIONS BY MR. TISI: 20 Q. You want me to answer {sic} 21 again? 22 A. If you could ask me again, yes, 23 please. 24 Q. Do you -- where the question is 25 whether or not an environmental factor or a</p>	<p>1 provide us with potential evidence when 2 looking at the association between exposure 3 and outcome. 4 Q. Okay. Has the FDA ever reached 5 out to you and asked your opinions on the 6 question of whether or not talc causes 7 ovarian cancer? 8 A. The FDA has not. 9 Q. Okay. You know IARC? 10 A. I know what IARC stands for, 11 but I don't know IARC. 12 Q. Okay. Do you -- have you -- 13 has the International Agency for Research on 14 Cancer, IARC, ever contacted you for any 15 reason to ask you to be involved in any 16 assessment of any exposure and cancer? 17 A. They have not. 18 Q. Have you written Health Canada 19 to express your opinions that you've given in 20 your report? 21 MS. MILLER: Objection. 22 THE WITNESS: Again, I don't 23 really know who Health Canada is. 24 QUESTIONS BY MR. TISI: 25 Q. Have you been provided with</p>
Page 163	Page 165
<p>1 substance causes harm, what science typically 2 relies on are observational studies and 3 biologic studies because you can't do 4 controlled trials? 5 MS. MILLER: Objection. 6 THE WITNESS: Okay. Again, we 7 have to just separate clinical trials. 8 That involves everything. 9 QUESTIONS BY MR. TISI: 10 Q. Right. 11 A. So if we're talking about an 12 observational study, for instance, if I'm 13 looking at a -- how a certain infectious 14 agent might affect an outcome in a patient 15 with cystic fibrosis, I wouldn't necessarily 16 do a randomized control trial where I give 17 someone an infection and I don't give 18 somebody else -- give another group an 19 infection and I look at an outcome 20 afterwards. 21 Q. Right. 22 A. So when there is a potential 23 for harm, a randomized control trial is 24 usually not done, so we rely on observational 25 studies, cohort and case-control studies, to</p>	<p>1 Health Canada's draft report on talcum powder 2 and ovarian cancer? 3 MS. MILLER: Objection. I 4 don't know what that means. 5 MR. TISI: You don't have to, 6 Counsel. 7 THE WITNESS: Is there 8 something that you want to show me? 9 QUESTIONS BY MR. TISI: 10 Q. Yeah. Sure. 11 A. We can look at it. 12 (Merlo Exhibit 13 marked for 13 identification.) 14 QUESTIONS BY MR. TISI: 15 Q. Showing you what I have marked 16 as Exhibit Number 13. 17 Have you seen this document 18 before? 19 A. I don't know. 20 Q. Is it of interest to you -- 21 MS. MILLER: Do you need some 22 time to flip through it? 23 THE WITNESS: I think so. 24 MR. TISI: No, I'm not -- I'm 25 not asking -- I'm asking if he ever</p>

42 (Pages 162 to 165)

Christian Merlo, M.D., MPH

Page 166	Page 168
<p>1 saw it -- Counsel, you know, honestly, 2 you really need to stop. You are 3 among the most unprofessional people I 4 have ever seen objecting in a case. 5 You inject yourself into almost every 6 question. 7 MR. LOCKE: Objection. 8 MS. SHARKO: Your ad hominem 9 and personal attacks -- 10 MR. TISI: Counsel, I was 11 called at the last deposition -- 12 MS. SHARKO: -- and venomous 13 comments, Mr. Tisi, are inappropriate. 14 MR. TISI: I was called -- 15 MS. SHARKO: Stop it 16 immediately. 17 MR. TISI: I was called at the 18 last deposition I was kicking her 19 under the table. I was called that I 20 speak to her as a -- you know, that I 21 speak to women this way. 22 Please don't talk to me about 23 ad hominem attacks. 24 MS. SHARKO: Well, those other 25 things you said are true. You were</p>	<p>1 THE WITNESS: Can you ask that 2 one more time? 3 QUESTIONS BY MR. TISI: 4 Q. Yeah. 5 Is it of interest to you what 6 other scientists and regulators have said 7 about the question you were asked to address 8 outside of litigation? 9 A. I'm curious about what others 10 say; however, in my review of the body of 11 medical literature that is out there today in 12 the published, peer-review literature, my 13 opinions are based on that. 14 Q. Okay. 15 A. I'm curious about other things, 16 but my opinions are based on what is peer 17 reviewed and published. 18 Q. Have you looked to see what 19 others have said about the body of evidence? 20 A. I don't know what you mean by 21 "others." 22 Q. Other scientists? Other 23 regulatory bodies? 24 A. You'd have to be more specific. 25 Q. Example, Health Canada?</p>
Page 167	Page 169
<p>1 kicking her. 2 MR. TISI: Oh, okay. I was not 3 kicking her under the table, and you 4 know that that's true -- not true. 5 MR. LOCKE: The witness is 6 entitled to read -- 7 MR. TISI: I'm not asking him a 8 question about the document. I'm 9 asking whether he ever saw the 10 document. 11 MS. MILLER: He needs to review 12 it to know if he ever saw it. 13 MR. TISI: No. I'm asking him 14 the questions. 15 MS. MILLER: Okay. 16 THE WITNESS: I'm looking to 17 see if I've seen this before. 18 I don't know. 19 QUESTIONS BY MR. TISI: 20 Q. Okay. Is it of interest to you 21 how other people outside of litigation, other 22 scientists, have evaluated the question of 23 whether or not talcum powder products cause 24 ovarian cancer? 25 MS. MILLER: Objection.</p>	<p>1 A. Health Canada? And again, I 2 have no idea who Health Canada is, whether or 3 not -- who is involved in Health Canada, 4 whether or not there are scientists involved, 5 whether or not -- who's there. I have no 6 idea. 7 Q. How about IARC? Did you review 8 the IARC 2010 report? 9 You were reviewing evidence 10 through 2006. Did you look at that? 11 A. Can you say that again? You 12 said two dates. 13 Q. Yes. 14 There was a 2010 report looking 15 at evidence up to 2006. 16 Did you look at that report? 17 A. I believe I did review that. 18 Q. And did you look any other 19 place to see what other scientists and 20 doctors have said about the issue? 21 A. Again, my job is not to have 22 opinions about other doctors or scientists. 23 My job is to give an opinion based on the 24 body of medical evidence, and that's what I 25 did.</p>

43 (Pages 166 to 169)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 170</p> <p>1 Q. Did you seek epidemio -- input 2 from your epidemiologic colleagues at Johns 3 Hopkins? 4 A. I seek -- I seek help from 5 epidemiologists all the time. 6 Q. For this report? 7 A. No. 8 Q. Okay. Did you speak to 9 Dr. Diette about your opinions in this case? 10 A. No. 11 Q. Did you speak to Dr. Szklo? Is 12 that his name? 13 A. Yeah. No. 14 Q. Did you speak to him? 15 A. No. No. 16 Q. Did you get permission of 17 approval from Johns Hopkins to participate in 18 this litigation? 19 MS. MILLER: Objection. 20 THE WITNESS: That's not 21 something that I would need approval 22 through Johns Hopkins for. 23 (Merlo Exhibit 14 marked for 24 identification.) 25</p>	<p style="text-align: right;">Page 172</p> <p>1 report. 2 A. I see it there on page 30. 3 Q. Yeah. So now can we agree it's 4 a seminal article? 5 MS. MILLER: Objection. 6 THE WITNESS: Well, it says, 7 "As Hill noted his seminal article." 8 QUESTIONS BY MR. TISI: 9 Q. So why was that such a hard 10 question to ask when -- answer when I asked 11 you what your opinion was? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. Did you need to see it in your 16 report in order to say what it says? 17 MS. MILLER: Objection. 18 THE WITNESS: I didn't 19 specifically remember saying that. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. It doesn't matter 22 because my question was, is it a seminal 23 article? I didn't ask you whether you said 24 it in your report. 25 Why is it so hard to answer a</p>
<p style="text-align: right;">Page 171</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Going back to your opinions 3 about talc, I'd like to attach as Exhibit 14 4 the Bradford Hill article I think you had in 5 front of you, but I'm going to attach it as 6 Exhibit Number 14. 7 A. Thank you. 8 Q. Is this the Bradford Hill 9 article that you have been referring to? 10 A. This is one of many of Bradford 11 Hill's articles. 12 Q. Okay. 13 A. This is his discussion of 14 the -- what we call nowadays the Bradford 15 Hill analysis. 16 Q. This is what you called the 17 seminal article, right? 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 THE WITNESS: Did I say that? 21 QUESTIONS BY MR. TISI: 22 Q. Yes, you did. 23 I don't know why that's a hard 24 question to answer, Doctor. Either you agree 25 to that or you don't, but it is in your</p>	<p style="text-align: right;">Page 173</p> <p>1 simple question as whether or not this is a 2 seminal article? 3 MS. MILLER: Objection. 4 Is that actually a question 5 you're asking? 6 MR. TISI: Yes. Absolutely. 7 QUESTIONS BY MR. TISI: 8 Q. Why is it so hard to answer 9 that question? 10 MS. MILLER: Objection. 11 MR. LOCKE: Objection. 12 QUESTIONS BY MR. TISI: 13 Q. Without seeing it in your 14 report? 15 MS. MILLER: Objection. 16 Now that the question has been 17 amended, still objection. 18 THE WITNESS: I thought you had 19 asked me if I said it, and I couldn't 20 remember -- 21 QUESTIONS BY MR. TISI: 22 Q. No. 23 A. -- if I actually said it. 24 Q. Actually, I asked you about ten 25 times: Is this a seminal article?</p>

44 (Pages 170 to 173)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 174</p> <p>1 And why is that such a hard</p> <p>2 question to answer?</p> <p>3 MS. MILLER: Objection.</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: It's probably one</p> <p>6 of his seminal articles.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Okay. You didn't address the</p> <p>9 question of biologic plausibility in your</p> <p>10 report, did you?</p> <p>11 A. So I did not speak about</p> <p>12 biologic plausibility in my report.</p> <p>13 Q. Okay. Did you -- I'm sorry.</p> <p>14 A. And -- you can go ahead.</p> <p>15 Q. Did you address the question of</p> <p>16 specificity?</p> <p>17 A. There are several aspects of</p> <p>18 the Bradford Hill considerations that are</p> <p>19 inherently irrelevant in the analysis.</p> <p>20 And the reason for that is if</p> <p>21 we -- if we just back up a little bit, first</p> <p>22 of all, Bradford Hill said that you need to</p> <p>23 have a clearcut association before even going</p> <p>24 into that and --</p> <p>25 Q. Aren't there plenty of examples</p>	<p style="text-align: right;">Page 176</p> <p>1 you?</p> <p>2 It's the second paragraph.</p> <p>3 A. I see that.</p> <p>4 Q. Right.</p> <p>5 What does the first paragraph</p> <p>6 say?</p> <p>7 A. We can read it if you'd like.</p> <p>8 Q. Why don't you.</p> <p>9 A. "I have no wish, nor the skill,</p> <p>10 to embark upon a philosophical discussion of</p> <p>11 the meaning of causation. The cause of</p> <p>12 illness may be immediate, indirect, it may be</p> <p>13 remote and indirect, underlying the observed</p> <p>14 association, but with the aims of</p> <p>15 occupational and almost synonymously</p> <p>16 preventive medicine in mind, the decisive</p> <p>17 question is whether the frequency of the</p> <p>18 undesirable event, B, will be influenced by a</p> <p>19 change in the environmental factor, A. How</p> <p>20 such a change exerts that influence may call</p> <p>21 for a great deal of research. However,</p> <p>22 before deducing causation and taking action,</p> <p>23 we shall not have invariably have to sit</p> <p>24 around awaiting the results of that research.</p> <p>25 The whole chain may have to be unraveled or a</p>
<p style="text-align: right;">Page 175</p> <p>1 of cases where an exposure -- there is no</p> <p>2 epidemiology studies where there is a</p> <p>3 clearcut association?</p> <p>4 I'll give you an example:</p> <p>5 Acetaminophen and liver disease, do you know</p> <p>6 of any epidemiology study which establishes</p> <p>7 that risk?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: I'm not here to</p> <p>10 give an opinion on --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. I know. But I want to know --</p> <p>13 A. -- acetaminophen and liver</p> <p>14 disease. I'd have to review the literature.</p> <p>15 Q. Well, where is your assessment?</p> <p>16 Where is the statement that</p> <p>17 before you apply the Bradford Hill factors</p> <p>18 that there must be a clearcut association?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It's actually</p> <p>21 said right in his article.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Actually, let's talk about that</p> <p>24 because you quoted part of the sentence</p> <p>25 there. You didn't quote the whole thing, did</p>	<p style="text-align: right;">Page 177</p> <p>1 few links may suffice. It will depend on</p> <p>2 circumstances."</p> <p>3 Q. Okay. So and circumstances</p> <p>4 are, there are sometimes we have a lot of</p> <p>5 evidence on one factor and a lot of evidence</p> <p>6 on another factor, right?</p> <p>7 MS. MILLER: Objection.</p> <p>8 QUESTIONS BY MR. TISI:</p> <p>9 Q. These are considerations. No</p> <p>10 one is more important than the other. And</p> <p>11 that was Dr. -- Sir Bradford Hill's point,</p> <p>12 right? These are considerations?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Once there is a</p> <p>15 clearcut association. And without</p> <p>16 that clearcut association, one could</p> <p>17 make the case of not even performing a</p> <p>18 Bradford Hill analysis.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. One can make the case;</p> <p>21 is that what he says?</p> <p>22 A. What he says is that in -- "in</p> <p>23 looking at causation, our observations reveal</p> <p>24 an association between two variables,</p> <p>25 perfectly clearcut and beyond what we would</p>

45 (Pages 174 to 177)

<p style="text-align: right;">Page 178</p> <p>1 care to attribute the play of chance." 2 Q. Now, before we discuss your 3 experience any further, I want to ask you to 4 go back to the front page of your report. 5 The front page of your report, 6 Exhibit 3, says -- actually, let me just go 7 back and ask this question. 8 On the Bradford Hill, you said 9 you didn't discuss the biologic evidence with 10 respect to talc and ovarian cancer, and it's 11 not in your report, correct? 12 MS. MILLER: Objection. 13 THE WITNESS: I did not. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. Did you -- I'm sorry, I 16 thought you were finished. 17 A. No, I did not discuss biologic 18 plausibility, and the reason is -- I said 19 before one could make the case of not even 20 performing a Bradford Hill analysis, but for 21 the sake of what other experts did, I went 22 through strength of association, consistency 23 and dose response. 24 And with a lack of strength of 25 association, with a lack of consistency</p>	<p style="text-align: right;">Page 180</p> <p>1 epidemiologic studies that looked at 2 different subtypes. 3 Q. And serous cancers were more 4 associated at a higher rate than other 5 ovarian cancers, correct? 6 A. It depends on which study we're 7 looking at. We'd have to go through all of 8 them. 9 Q. Okay. But would it -- you 10 didn't do that for the purposes of -- you 11 didn't look at whether or not the evidence -- 12 there was evidence of specificity to -- for 13 example, epithelial ovarian cancer as opposed 14 to other kinds of cancers? 15 A. That's not -- 16 MS. MILLER: Objection. 17 THE WITNESS: That's not 18 exactly what Bradford Hill is talking 19 about when talking about specificity. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. 22 A. The term "specificity" is 23 referred -- the term "specificity" is talking 24 about a specific exposure causing a certain 25 disease, and there are certain diseases that</p>
<p style="text-align: right;">Page 179</p> <p>1 between studies and with a lack of dose 2 response, biologic plausibility doesn't 3 matter because there's no causal association 4 between talcum powder and ovarian cancer 5 based on the medical literature. 6 Q. So let me ask you this: Is the 7 issue of specificity important? 8 For example, wouldn't it be 9 important to consider whether or not the 10 studies that did show an association were 11 specific to a particular type of cancer and 12 not others? Because that would -- that 13 question would argue against the issue of 14 recall bias, for example. 15 A. You asked several questions 16 there, so if you could just break that down, 17 it would be helpful. 18 Q. I'll break it down. 19 Wouldn't it be important to 20 consider the issue of specificity? 21 You know that many of these 22 studies broke down their analysis -- tried to 23 break down their analysis by subtype of 24 ovarian cancer, correct? 25 A. There were several</p>	<p style="text-align: right;">Page 181</p> <p>1 have lots of things that can cause them. 2 But if there is one disease 3 that only one exposure causes, then that's 4 what specificity means. Not specificity in 5 the different type of ovarian cancer. 6 Q. So you don't think it's 7 relevant to look at whether or not a 8 association is correlated more specifically 9 with the type of ovarian cancer as opposed to 10 ovarian cancer generally for the purposes of 11 trying to figure out whether or not there 12 really was bias in these studies? 13 MS. MILLER: Objection. 14 THE WITNESS: I don't even 15 understand what you just asked me. 16 QUESTIONS BY MR. TISI: 17 Q. Okay. You didn't look at -- 18 you didn't look at analogy, did you? 19 MS. MILLER: Objection. 20 THE WITNESS: Analogy, again, 21 is -- you'd have to look at something 22 exactly similar to talc, and there's 23 nothing analogous there that -- 24 QUESTIONS BY MR. TISI: 25 Q. But you didn't address it in</p>

Christian Merlo, M.D., MPH

Page 182	Page 184
<p>1 your report is my question.</p> <p>2 A. I did not address it.</p> <p>3 Q. And you didn't address the</p> <p>4 specificity factor, correct?</p> <p>5 A. Again, specificity in this</p> <p>6 case, as in cases of other diseases where</p> <p>7 there are a number of potential risk factors,</p> <p>8 it's not appropriate to look at specificity.</p> <p>9 Q. Doctor, my question is: You</p> <p>10 didn't address it in your report at all?</p> <p>11 MS. MILLER: Please don't</p> <p>12 interrupt him.</p> <p>13 THE WITNESS: It's inherent in</p> <p>14 there.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Okay. It's not addressed</p> <p>17 specifically in your report, is it?</p> <p>18 MS. MILLER: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. You didn't say, "I address the</p> <p>21 specificity factor, and it doesn't apply or</p> <p>22 it does apply" for the following reasons?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: Again, there is</p> <p>25 not a line item that says specificity,</p>	<p>1 A. So, first of all, it says</p> <p>2 "perfectly clearcut."</p> <p>3 Q. I understand you quoted him,</p> <p>4 and I'm asking you -- I'm not asking you what</p> <p>5 he meant because I think it's -- article is</p> <p>6 pretty clear when he meant.</p> <p>7 I'm asking you: In the next</p> <p>8 sentence where you pulled out the word</p> <p>9 "clearcut," what do you mean?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: One that is</p> <p>12 beyond that we would attribute to the</p> <p>13 play of chance.</p> <p>14 And based on the body of</p> <p>15 medical evidence and the inconsistency</p> <p>16 within certain study designs and</p> <p>17 between certain study designs, the</p> <p>18 association is not clearcut.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. How do you define "clearcut"?</p> <p>21 In other words, when you say</p> <p>22 "play of chance," that's a statistical</p> <p>23 concept.</p> <p>24 Chance is defined typically by</p> <p>25 P value, correct, of .05?</p>
Page 183	Page 185
<p>1 and because of -- and the reason for</p> <p>2 that is because there's no strength of</p> <p>3 association, there's no consistency</p> <p>4 within studies, and there's no dose</p> <p>5 response to -- within the studies.</p> <p>6 And so without those things --</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Okay.</p> <p>9 A. Without those things, the other</p> <p>10 considerations are -- are -- you can't get</p> <p>11 there.</p> <p>12 Q. Okay. Let me go to page 30 of</p> <p>13 your report. There's a paragraph here that</p> <p>14 deals with the issue -- it's the seminal --</p> <p>15 the seminal article paragraph.</p> <p>16 A. Sure.</p> <p>17 Q. All right? It says, "Before</p> <p>18 evaluating causation, study must reveal an</p> <p>19 association between two variables, preferably</p> <p>20 clearcut and beyond that -- beyond what we</p> <p>21 would care to attribute the play of chance.</p> <p>22 As I discuss further below, the requirement</p> <p>23 is likely not satisfied here because we are</p> <p>24 not presented with a clearcut association."</p> <p>25 How do you define clearcut?</p>	<p>1 A. Chance is defined as a -- about</p> <p>2 a 1 and 20 chance.</p> <p>3 Q. Right. A .05 P value, right?</p> <p>4 A. Statistically, yes.</p> <p>5 Q. Okay. And so is that what you</p> <p>6 mean when you say "a clearcut association"?</p> <p>7 You're talking a statistically</p> <p>8 significant association, correct?</p> <p>9 A. I'm not. No, I'm not.</p> <p>10 MS. MILLER: Objection.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. So what do you mean</p> <p>13 by -- when you say --</p> <p>14 A. I wasn't finished.</p> <p>15 Q. Okay.</p> <p>16 A. Well, I'm trying to get at what</p> <p>17 you mean by clearcut association.</p> <p>18 MS. MILLER: Okay. Objection.</p> <p>19 Asked and answered.</p> <p>20 THE WITNESS: One where there</p> <p>21 is consistency between -- and in this</p> <p>22 instance, in this specific instance,</p> <p>23 one where there's consistency between</p> <p>24 different types of studies and</p> <p>25 different types of --</p>

47 (Pages 182 to 185)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 186</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. I'm not asking you in this 3 case. 4 I'm asking you, generally 5 speaking, when you say the requirement is not 6 satisfied here -- okay, because it's not 7 presented with a clearcut association. 8 I'm asking you, generally 9 speaking, if you're -- if I'm a student at 10 Johns Hopkins and I see this sentence and I 11 ask you -- raise my hand and say, "Doctor, 12 can you tell me what is meant by a clearcut 13 association? What is meant by that?" how 14 would you -- what would you tell me? 15 Without reference to any 16 specific case, what is meant by clearcut 17 association? 18 MS. MILLER: Objection. 19 THE WITNESS: I would say it 20 depends. It depends on what we're 21 looking at, what exposure and outcome 22 relationship we're looking at. It 23 depends what's available in the 24 medical evidence. It depends on how 25 the study or the initial work was set</p>	<p style="text-align: right;">Page 188</p> <p>1 study types over a period of time that 2 show -- some show something and some show 3 another, that's inconsistent, and that -- 4 Q. What do they show here that 5 makes them inconsistent? 6 MS. MILLER: Objection. He's 7 really -- please let him finish his 8 sentences. 9 THE WITNESS: Can you be more 10 specific? 11 QUESTIONS BY MR. TISI: 12 Q. Yeah. You just made -- 13 MS. MILLER: You were in the 14 middle of a sentence. 15 QUESTIONS BY MR. TISI: 16 Q. You just made the statement, 17 "Some show something and some show another, 18 that's inconsistent." 19 My question is, what: Here -- 20 what is the "something" you're referring to? 21 A. Well, if we're specifically 22 talking about the potential causal 23 association between talcum powder and ovarian 24 cancer, there are hospital-based case-control 25 studies that are all not statistically</p>
<p style="text-align: right;">Page 187</p> <p>1 up. It depends on whether or not bias 2 and confounding were taken care of. 3 It depends on so many factors 4 that it makes it impossible to even 5 answer that question. 6 QUESTIONS BY MR. TISI: 7 Q. Would it matter whether or not 8 the study was replicated, in other words, 9 that there was more than one study? 10 A. So sometimes replication can 11 help with -- 12 Q. Is it necessary? 13 A. So I was -- wasn't done. 14 Q. Okay. 15 A. So sometimes replication can be 16 helpful. 17 Is it necessary? Not 18 necessarily, because you could have one very, 19 very, very good initial study where you've 20 taken care of lots of things like bias and 21 confounding and random error and the analysis 22 is fine, and so you do come up with, "Hey, we 23 think this association is real. Let's do 24 further studies." 25 But when you look at different</p>	<p style="text-align: right;">Page 189</p> <p>1 significant. 2 There are population-based 3 case-control studies; some are statistically 4 significant, some are not. 5 There are cohort studies, four 6 of them, all not statistically significant. 7 And so when you break down this 8 association in trying to look at causality, 9 when you break down things -- when you break 10 down this by study design, there's a 11 difference. There's an inconsistency between 12 cohort studies and cases controls. There's 13 an inconsistency between population-based 14 case controls and hospital-based case 15 controls. 16 Q. Okay. So if I understand you 17 correctly -- 18 A. And so the association is not 19 clearcut. 20 Q. Okay. So if I can go to 21 page 45 of your report -- I was going to 22 discuss this later, but this seems to be a 23 perfect time. 24 On page 45 you state, "It is 25 important to remember, contrary to the</p>

Christian Merlo, M.D., MPH

Page 190	Page 192
<p>1 suggestion of plaintiffs' experts, in 2 parentheses, that this criterion" -- and the 3 criterion we're talking about is 4 consistency -- "to weigh in favor finding 5 causal association must be consistency in 6 statistically significant associations." 7 And you have that in bold, 8 correct? 9 A. Are we reading the first 10 sentence? 11 Q. Correct. 12 A. Okay. Can I read it? 13 Q. Sure. 14 A. You want me to read it out 15 loud? 16 Q. No, I just read it. 17 A. I was flipping through, trying 18 to -- 19 Q. That's okay. Let me read it 20 again. 21 You state, "It is important to 22 remember, contrary to the suggestion of 23 several of plaintiffs' experts, that for this 24 criterion to weigh in favor of finding a 25 causal relationship, there must be</p>	<p>1 difficult to prove causality. 2 QUESTIONS BY MR. TISI: 3 Q. So is an underlying 4 principle -- you say it's important to 5 remember here -- that a statistically 6 significant result is inconsistent with a 7 statistically insignificant result? 8 MR. LOCKE: Objection. 9 MS. MILLER: Objection. 10 THE WITNESS: Can you say that 11 again? 12 QUESTIONS BY MR. TISI: 13 Q. Yes. 14 If one study shows a 15 statistically significant result and one a 16 statistically insignificant result, are they 17 by definition inconsistent? 18 MS. MILLER: Objection. 19 THE WITNESS: I think it 20 depends. If you get 20 studies, and 21 10 of them are statistically 22 significant and 10 are not 23 statistically significant, that's 24 inconsistent. 25</p>
Page 191	Page 193
<p>1 consistency in statistically significant 2 associations." 3 And you have that in bold, 4 correct? 5 A. That's correct. 6 Q. Okay. And the report that you 7 cite there is -- I'm sorry, you don't cite 8 anything for that. 9 Can you tell me your basis for 10 that -- 11 MS. MILLER: Objection. 12 QUESTIONS BY MR. TISI: 13 Q. -- statement? 14 MS. MILLER: Objection. 15 THE WITNESS: As an 16 epidemiologist, if we are -- if I'm 17 asked to weigh the body of evidence 18 and there is inconsistency in 19 statistical significance, it makes it 20 impossible to conclude a causal 21 relationship between exposure and 22 outcome. 23 Because if you're not showing 24 consistent statistical significance, 25 then that association becomes very</p>	<p>1 QUESTIONS BY MR. TISI: 2 Q. Okay. Have you done a 3 meta-analysis? 4 A. I have. 5 Q. Okay. Have you ever published 6 a meta-analysis? 7 A. I have not. 8 Q. Are you a biostatistician? 9 A. I've taken courses in 10 biostatistics. I don't consider myself a 11 biostatistician, but oftentimes there is a 12 link between epidemiology and biostatistics. 13 So I do a lot of my statistical analysis 14 myself. I don't consider myself a 15 biostatistician, though. 16 Q. Okay. Do you hold yourself out 17 to colleagues as a biostatistician or a 18 statistician? 19 MS. MILLER: Objection. Asked 20 and answered. 21 THE WITNESS: Again, I consider 22 myself an epidemiologist, and we do 23 have training in biostatistics, and 24 they're not -- they're oftentimes 25 very, very linked. I don't call</p>

49 (Pages 190 to 193)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 194</p> <p>1 myself a biostatistician. 2 QUESTIONS BY MR. TISI: 3 Q. Okay. By virtue of being -- 4 would you agree with me that though there is 5 overlap between the two professions -- you 6 guys need each other, right? -- it is not 7 necessarily the case that a biostatistician 8 is an epidemiologist and an epidemiologist is 9 a biostatistician? 10 MS. MILLER: Objection. 11 MR. LOCKE: Objection. 12 THE WITNESS: That's pretty 13 general. I mean, there are probably 14 people out there that are both. 15 QUESTIONS BY MR. TISI: 16 Q. And there are some that are one 17 and not the other, correct? 18 A. I have no idea. It's not 19 something I think about. 20 Q. Okay. What is the latency of 21 ovarian cancer between something that may 22 cause it and something that -- and the onset 23 of disease? 24 MS. MILLER: Objection. 25 THE WITNESS: I don't think</p>	<p style="text-align: right;">Page 196</p> <p>1 an infection at age 1, and we follow 2 them for 20 years. 3 Sometimes we ask about things 4 and we follow people for an 5 appropriate amount of time, but they 6 may have been exposed to that prior to 7 that. So it really depends. 8 QUESTIONS BY MR. TISI: 9 Q. Now, I asked you a couple of 10 questions before about the role of 11 professional judgment in looking at the 12 Bradford Hill guidelines. 13 Do you remember those 14 questions? 15 A. Not specifically, no. 16 Q. Okay. Well, I'm going to turn 17 to that question now. I told you I'd come 18 back to it, and I'm going to come back to it 19 now. 20 Did you use -- when looking at 21 all of this evidence that you looked at, did 22 you use any degree of professional judgment 23 in analyzing the question of whether or not 24 talcum powder products cause ovarian cancer? 25 A. I don't know what you mean by</p>
<p style="text-align: right;">Page 195</p> <p>1 anybody knows the latency of ovarian 2 cancer and -- first of all, you'd have 3 to not just say something, you'd have 4 to say what risk factor you're talking 5 about. Is it risk factor X, and do we 6 know that, has that been studied? 7 So talking about the latency of 8 ovarian cancer with such generalities, 9 I don't think anybody can answer that. 10 QUESTIONS BY MR. TISI: 11 Q. Well, is that important to 12 consider when looking at cohort studies and 13 to see whether or not they're long enough? 14 MS. MILLER: Objection. 15 THE WITNESS: So that depends. 16 It depends on whether -- certainly it 17 does depend on how long you follow 18 someone in a cohort study, yeah, but 19 also depends on when potentially the 20 exposure could have started. 21 For instance, in cohort studies 22 that I have performed in patients with 23 cystic fibrosis who have had lung 24 transplants, some are born with 25 conditions. Some are -- some acquire</p>	<p style="text-align: right;">Page 197</p> <p>1 "professional judgment." 2 What I did is I reviewed the 3 literature. I read the articles. I looked 4 at how the studies were designed, whether or 5 not they controlled for bias or adjusted for 6 potential confounding, sample size in 7 studies, the differences in population 8 between the case-control studies, the number 9 of people in cohort studies, how long people 10 were followed. 11 So I don't know what you mean 12 by professional judgment, but that's what I 13 did. 14 Q. Well, I mean, you provided a 15 list of people -- you provided a list of 16 things that you did. 17 Is there anything on that list 18 that you think that any of plaintiffs' 19 experts did not do? 20 A. You'd have to get way more 21 specific about that. 22 Q. I'm asking you. Did you -- you 23 reviewed their reports. 24 Is there anything -- any part 25 of you -- did they look at bias, study</p>

Christian Merlo, M.D., MPH

Page 198	Page 200
<p>1 design, number of patients enrolled, all 2 those things that you just mentioned? You 3 listed a bunch of them. 4 Can you think of any gap in 5 their report where they didn't consider the 6 things you considered? 7 MS. MILLER: Objection. 8 THE WITNESS: You'd have to 9 show where what we're -- what you're 10 asking me about. 11 QUESTIONS BY MR. TISI: 12 Q. No, I'm not going to do that, 13 Doctor. 14 I'm asking can you think of any 15 as you sit here right now? 16 MS. MILLER: Objection. Asked 17 and answered. 18 THE WITNESS: Without us going 19 through the specifics, I can't answer 20 that general question. 21 QUESTIONS BY MR. TISI: 22 Q. So do you agree that it is 23 well-understood that Hill's postulates are 24 ones in which experts will always apply 25 professional judgment?</p>	<p>1 because it's one of my textbooks. I'm 2 not here to provide opinions on 3 whether or not I think a textbook is 4 authoritative. I'm here to give you 5 my opinion on the medical evidence. 6 (Merlo Exhibit 22 marked for 7 identification.) 8 QUESTIONS BY MR. TISI: 9 Q. Well, you cited a textbook -- 10 okay. Let me ask you this. Let me look at 11 Exhibit 22. 12 Here is a -- it's called 13 Epidemiology, Concepts and Methods. 14 Do you see that, Doctor? I 15 just included the cover page. 16 MS. MILLER: I'm going to 17 object to this exhibit. It is two 18 pages pulled from a book, and the 19 second page ends in the middle of a 20 sentence. 21 MR. TISI: I'm not asking that 22 question. Why don't you -- 23 MS. MILLER: I just don't think 24 it's a proper exhibit. 25 MR. TISI: I know you don't</p>
Page 199	Page 201
<p>1 A. I don't -- what are you 2 referring to? 3 Q. Well, let me ask you this: In 4 your report you refer oftentimes to a 5 textbook by William Oleckno. 6 Do you know that -- 7 A. The textbook? 8 Q. Yeah. 9 A. I do know that textbook. 10 Q. Okay. 11 MS. MILLER: If we're going to 12 move on to a new subject, lunch has 13 been waiting for a while, so maybe -- 14 MR. TISI: Well, I just opened 15 up a can of worms here, so I'm going 16 to just -- give me about five, ten 17 minutes, and we'll get done with this 18 section. 19 QUESTIONS BY MR. TISI: 20 Q. You cited it several times 21 because you find that that is an 22 authoritative textbook in the area of 23 epidemiology? 24 MS. MILLER: Objection. 25 THE WITNESS: I cited it</p>	<p>1 think so. You don't think anything is 2 proper. 3 But I'm going to ask -- why 4 don't you wait until I ask my 5 question, and then we can figure out 6 whether or not I'm doing something 7 improper or not. 8 MS. MILLER: I'm objecting to 9 the exhibit, not to the question. 10 MR. TISI: Okay. That's fine. 11 I'm objecting to your objections 12 because I think they're ridiculous. 13 MS. SHARKO: Please be 14 professional. 15 MR. TISI: Oh, I'm very 16 professional, Counsel, except when 17 somebody is an intrusive as Ms. Miller 18 has been in any deposition I've been 19 involved with. 20 MS. SHARKO: That's so 21 inappropriate. 22 MR. TISI: I know you think it 23 is inappropriate. 24 MR. LOCKE: Objection. I'm 25 objecting to the exhibit as well.</p>

51 (Pages 198 to 201)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 202</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. So there is a paragraph here on</p> <p>3 page 188, and I'm going to ask you whether</p> <p>4 you agree with it or not, and I'm going to</p> <p>5 ask you to read it.</p> <p>6 It says --</p> <p>7 A. So what am I looking at here?</p> <p>8 Q. On page 188, Chapter 7.</p> <p>9 A. No, what is this exhibit?</p> <p>10 Q. It is a -- it is a -- it is a</p> <p>11 page of Chapter 7, Association, Causation in</p> <p>12 Epidemiology.</p> <p>13 There's a chapter from</p> <p>14 Dr. Oleckno's book.</p> <p>15 A. Okay. So I see a photocopy of</p> <p>16 what appears to be the cover of the book.</p> <p>17 Q. The first chapter -- the first</p> <p>18 page of the chapter.</p> <p>19 A. Of Chapter 7.</p> <p>20 Q. And there's a paragraph on</p> <p>21 Bradford Hill. Okay?</p> <p>22 And I'm going to ask you about</p> <p>23 the paragraph that he writes on Bradford</p> <p>24 Hill. It's the only paragraph that he talks</p> <p>25 about Bradford Hill.</p>	<p style="text-align: right;">Page 204</p> <p>1 association, correct? Temporal sequence,</p> <p>2 temporality?</p> <p>3 A. We're talking about that last</p> <p>4 sentence there?</p> <p>5 Q. Yes, correct.</p> <p>6 A. "In the end, the process of</p> <p>7 determining causation is largely subjective</p> <p>8 except for the first guideline, which is</p> <p>9 actually a requirement."</p> <p>10 Q. And the first guideline is</p> <p>11 correct temporal sequence?</p> <p>12 A. I'm not sure what it's</p> <p>13 referring to, but I see "correct temporal</p> <p>14 sequence" right below that.</p> <p>15 Q. All right. Do you disagree</p> <p>16 that the determination of causation is</p> <p>17 largely subjective, if using Hill's</p> <p>18 postulates?</p> <p>19 A. Can you ask that again?</p> <p>20 Q. Yeah.</p> <p>21 Do you believe that the</p> <p>22 ultimate decision on causation requires -- is</p> <p>23 a subjective look at the evidence?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: I'm not -- I'm</p>
<p style="text-align: right;">Page 203</p> <p>1 MS. MILLER: Objection. We --</p> <p>2 MR. TISI: That's fine.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. "On 1965, Sir Bradford Hill,</p> <p>5 professor emeritus at the medical statistics</p> <p>6 with the University of London, delivered a</p> <p>7 landmark address where he outlined nine</p> <p>8 criteria that could be used to determine if</p> <p>9 statistical associations were likely to</p> <p>10 represent causal associations. His reasoning</p> <p>11 built on the earlier work of others such as</p> <p>12 John Stuart Mill, who in 1856 had defined</p> <p>13 several canons from which causal</p> <p>14 relationships could be deduced. Over the</p> <p>15 years, many authors have articulated or</p> <p>16 modified Hill's basic criteria which have</p> <p>17 become known as Hill's postulates. Using</p> <p>18 these as a focal point, the following six</p> <p>19 guidelines should be helpful in deciding</p> <p>20 whether or not statistical associations are</p> <p>21 likely to represent causal associations. In</p> <p>22 the end, the process of determining causation</p> <p>23 is largely subjective except for the first</p> <p>24 guideline, which is actually a requirement."</p> <p>25 And that's temporal</p>	<p style="text-align: right;">Page 205</p> <p>1 sorry, I'm just not understanding what</p> <p>2 you're asking.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Okay. Do you agree with the</p> <p>5 sentence that -- the last sentence. "In the</p> <p>6 end, the process of determining causation is</p> <p>7 largely subjective except for the first</p> <p>8 guideline, which is actually a requirement"?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I see that</p> <p>11 sentence there, and I see that it</p> <p>12 says, "In the end, the process of</p> <p>13 determining causation is largely</p> <p>14 subjective except for the first</p> <p>15 guideline, which is actually a</p> <p>16 requirement."</p> <p>17 What is the question?</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. My question: Do you agree with</p> <p>20 that sentence?</p> <p>21 A. It's written there.</p> <p>22 Q. Do you agree with it?</p> <p>23 A. I think it depends. I think</p> <p>24 it -- it depends on what we're looking at.</p> <p>25 It depends on the exposure outcome</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 206</p> <p>1 relationship. It's a very, very general 2 question -- 3 Q. Okay. 4 A. -- and a photocopy of one page 5 in a textbook that I don't have memorized. 6 (Merlo Exhibit 23 marked for 7 identification.) 8 QUESTIONS BY MR. TISI: 9 Q. Well, let's look at exhibit 10 number -- let's look at Exhibit Number 23, 11 which is the textbook by Dr. Gordis. And I 12 do have the whole chapter here, so feel free 13 to thumb through it. 14 MS. MILLER: Is this a good 15 time for lunch? You said it was just 16 five minutes. It's been five minutes. 17 MR. TISI: Okay. 18 MS. MILLER: Do you want to do 19 that after lunch? 20 MR. TISI: I would prefer to 21 finish it now, but if you feel like 22 you're -- you absolutely need to have 23 lunch right now, if the witness does, 24 I'm absolutely okay with that. 25 MS. MILLER: We've been going</p>	<p style="text-align: right;">Page 208</p> <p>1 Q. And Dr. Gordis, again, is 2 the -- was the head of the department for 3 epidemiology at Johns Hopkins, correct? 4 A. You know, I don't remember. I 5 know he taught one of my courses. 6 Q. He's a big deal, isn't he? 7 A. I can't remember if he was the 8 head of the department of epidemiology. 9 Q. He's a big deal. He was well 10 known, a well-known epidemiologist? 11 A. I took his course, I mean, but 12 I don't know what you mean by "big deal." I 13 don't -- 14 Q. You don't think he's -- okay. 15 Do you -- you don't understand what his 16 reputation was in the community? 17 A. Again -- 18 MR. LOCKE: Objection. 19 MS. MILLER: Objection. 20 QUESTIONS BY MR. TISI: 21 Q. Let me ask you -- what you 22 think you're here for, candidly, is not as 23 important to me as you answering my 24 questions. Because what I may think 25 important or you may think important and what</p>
<p style="text-align: right;">Page 207</p> <p>1 an hour and 40 minutes. That's a long 2 time. 3 What do you think, Susan? 4 MS. SHARKO: Yeah. 5 MR. TISI: It's up to you. I 6 said I'm okay with it. 7 MS. SHARKO: Thank you. 8 VIDEOGRAPHER: All right. The 9 time is 12:18 p.m. We're going off 10 the record. 11 (Off the record at 12:17 p.m.) 12 VIDEOGRAPHER: The time is 13 12:57 p.m., and we're back on the 14 record. 15 QUESTIONS BY MR. TISI: 16 Q. Doctor, before the break I was 17 about to hand you Exhibit Number 23. And 18 these are -- just for the record, I had these 19 kind of preorganized, so we're going to skip 20 exhibits. So you may see me bouncing around 21 a little bit. There's not necessarily a 22 rhyme or reason to that. 23 So this is Exhibit Number 23. 24 This is Chapter 14 from the Gordis textbook. 25 A. Sure.</p>	<p style="text-align: right;">Page 209</p> <p>1 Ms. Miller may think important are different. 2 So I'm going to ask this 3 question: Do you have an understanding of 4 the reputation of Dr. Gordis? 5 MS. MILLER: Objection. 6 MR. LOCKE: Objection. 7 THE WITNESS: And I'll state 8 that I took a course by Dr. Gordis in 9 epidemiology. It was Epidemiology I. 10 And I will state again that I'm 11 not here to give an opinion on whether 12 or not I think Dr. Gordis or anyone 13 has a reputation or a good reputation 14 or a great reputation or whatever. 15 QUESTIONS BY MR. TISI: 16 Q. So you have -- you're agnostic 17 to who Dr. -- Dr. Gordis' qualifications? 18 A. What I can say -- 19 MS. MILLER: Objection. 20 THE WITNESS: I didn't say 21 that. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. So what is your 24 assessment? 25 MS. MILLER: Objection.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 210</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. What is your assessment then?</p> <p>3 MS. MILLER: Same objection.</p> <p>4 THE WITNESS: What I can say --</p> <p>5 what I can say is that he was a</p> <p>6 professor of mine. I learned a great</p> <p>7 deal from the class that I took that</p> <p>8 he taught, and he was a member of the</p> <p>9 faculty at Johns Hopkins Bloomberg</p> <p>10 School of Public Health.</p> <p>11 But as far as reputation and</p> <p>12 those things, that's -- I don't have</p> <p>13 an opinion about it.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Do you consider him an</p> <p>16 authority?</p> <p>17 MS. MILLER: Objection.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. You personally consider him an</p> <p>20 authority?</p> <p>21 MS. MILLER: Objection.</p> <p>22 THE WITNESS: I consider</p> <p>23 Dr. Gordis a professor of mine.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Well, he was a professor of</p>	<p style="text-align: right;">Page 212</p> <p>1 you have an opinion, I'm entitled to ask it.</p> <p>2 Unless counsel tells you that you can't</p> <p>3 answer it, you have to answer it.</p> <p>4 So my question is: Do you have</p> <p>5 an opinion as to whether or not Dr. -- from</p> <p>6 your perspective, he is an authority in the</p> <p>7 field of epidemiology?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. MILLER: I'm going to</p> <p>11 object on multiple grounds, one of</p> <p>12 which is asked and answered.</p> <p>13 THE WITNESS: He was a</p> <p>14 professor of mine who taught a course</p> <p>15 in Epidemiology I, we used his</p> <p>16 textbook as one of the references</p> <p>17 during the class, and I had good</p> <p>18 interactions with him during the</p> <p>19 class. That's what I have to say</p> <p>20 about Dr. Gordis.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. So let's look at Chapter 14,</p> <p>23 Association to Causation: Deriving</p> <p>24 Inferences From Epidemiologic Studies.</p> <p>25 That's what we're doing here</p>
<p style="text-align: right;">Page 211</p> <p>1 yours, and so I'm asking you: Do you</p> <p>2 consider him to be an authority in the field</p> <p>3 of epidemiology?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Dr. Gordis was an</p> <p>6 epidemiologist. He's since passed.</p> <p>7 And he taught a course that I took,</p> <p>8 and that's that.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. So you don't have any feelings</p> <p>11 about his qualifications one way or the</p> <p>12 other?</p> <p>13 A. It's not something I consider.</p> <p>14 It's not something that I -- he taught me a</p> <p>15 class, and I learned a lot from it.</p> <p>16 Now, whether or not he's an</p> <p>17 authority is -- that's -- I don't have an</p> <p>18 opinion -- I'm not here to give an opinion</p> <p>19 about --</p> <p>20 Q. I didn't ask you whether you</p> <p>21 think you're here to give an opinion about</p> <p>22 that. I'm here to ask you questions, and I'm</p> <p>23 entitled to ask you questions. Okay?</p> <p>24 And so if you -- if you don't</p> <p>25 have an opinion, that's one thing. But if</p>	<p style="text-align: right;">Page 213</p> <p>1 today, right? We're deriving -- we're seeing</p> <p>2 whether or not there's an inference from the</p> <p>3 epidemiologic studies?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: Can you ask me</p> <p>6 that question --</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Actually, I don't even need to.</p> <p>9 Let's move on.</p> <p>10 Can you look at the page --</p> <p>11 it's 260, please. Actually, go to page 251.</p> <p>12 A. 251. Got it.</p> <p>13 Q. Do you see on page 251 -- and</p> <p>14 I'm not going to ask you to read it.</p> <p>15 Actually, if you go to page 250 --</p> <p>16 MS. MILLER: I'm sorry, Chris,</p> <p>17 I don't think we got a copy.</p> <p>18 MR. TISI: Oh, I'm sorry.</p> <p>19 That's my bad. Here you go.</p> <p>20 MS. MILLER: Thank you so much.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. There's a section called</p> <p>23 Evidence for Causal Relationship, and then it</p> <p>24 has guidelines for judging whether an</p> <p>25 observed association is causal. On page 250.</p>

Christian Merlo, M.D., MPH

Page 214	Page 216
<p>1 A. 250 now.</p> <p>2 Q. Yeah.</p> <p>3 A. 250. Okay. I got it.</p> <p>4 Q. And see Table 14.1 in those</p> <p>5 lists, the five aspects -- excuse me -- the</p> <p>6 nine aspects of Bradford Hill?</p> <p>7 A. Yeah, let me just look at them</p> <p>8 because there are nine there. I just want to</p> <p>9 make sure that those are the nine Bradford</p> <p>10 Hill criteria.</p> <p>11 MR. LOCKE: Objection to the</p> <p>12 use of this exhibit.</p> <p>13 THE WITNESS: So I see these</p> <p>14 nine -- I see Table 14.1 stating</p> <p>15 "guidelines for judging whether an</p> <p>16 observed association is causal," and I</p> <p>17 see nine lines there.</p> <p>18 But there are some lines that</p> <p>19 are not necessarily those that are --</p> <p>20 those that Bradford Hill spoke about</p> <p>21 in his article.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. So if you go to the</p> <p>24 last -- after discussing the nine that he</p> <p>25 discusses, at the very end it has a</p>	<p>1 information needed for doing so. The</p> <p>2 preceding list should therefore be</p> <p>3 considered -- should therefore be considered</p> <p>4 to be only guidelines that can be of most</p> <p>5 value when coupled with reasoned judgment</p> <p>6 about the entire body of available evidence</p> <p>7 in making decisions about causation."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes, you did.</p> <p>10 Q. Okay. Do you agree with that</p> <p>11 statement?</p> <p>12 MS. MILLER: Objection.</p> <p>13 MR. LOCKE: Objection.</p> <p>14 THE WITNESS: I mean, there are</p> <p>15 so many statements in there, you'd</p> <p>16 have to ask me specifically if I agree</p> <p>17 or disagree with --</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Well, do you agree with the</p> <p>20 statement that reasoned judgment is important</p> <p>21 when interpreting epidemiologic evidence?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I didn't write</p> <p>24 this, and I don't know exactly what</p> <p>25 the definition of reasoned judgment</p>
Page 215	Page 217
<p>1 conclusion.</p> <p>2 A. Who are you referring to,</p> <p>3 Dr. Gordis or --</p> <p>4 Q. Dr. Gordis.</p> <p>5 A. -- Bradford Hill?</p> <p>6 Q. Dr. Gordis. At the conclusion</p> <p>7 on page 260.</p> <p>8 A. So we're going to 260 now?</p> <p>9 Q. Uh-huh.</p> <p>10 A. Okay. 260.</p> <p>11 Q. Right.</p> <p>12 There's a conclusion there,</p> <p>13 right?</p> <p>14 A. I see "conclusion," the word,</p> <p>15 yes.</p> <p>16 Q. Okay. And I'm going to read</p> <p>17 it -- the paragraph in the conclusion and see</p> <p>18 whether you agree with it.</p> <p>19 "Although causal guidelines</p> <p>20 discussed in this chapter are often referred</p> <p>21 to as criteria, the term does not seem</p> <p>22 entirely appropriate. Although it may be a</p> <p>23 desirable goal to place causal inferences on</p> <p>24 a firm quantitative and structural</p> <p>25 foundation, at present we do not have all the</p>	<p>1 in -- that's a very vague term.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay.</p> <p>4 A. And it's going to be impossible</p> <p>5 to answer that, because I don't know what the</p> <p>6 definition of reasoned judgment is.</p> <p>7 (Merlo Exhibit 24 marked for</p> <p>8 identification.)</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Okay. That's fine.</p> <p>11 Go to page -- we'll discuss</p> <p>12 this real quickly.</p> <p>13 Oh. On page 2 of your report,</p> <p>14 footnote 1, you refer to a lesson from the</p> <p>15 CDC publication. I'd like to mark that as</p> <p>16 Exhibit Number 24.</p> <p>17 A. Where are we now?</p> <p>18 Q. Page 2 of your report, footnote</p> <p>19 1.</p> <p>20 A. Correct. Yes. I have it.</p> <p>21 Q. It refers to a CDC publication?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay? I marked that as Exhibit</p> <p>24 Number 24.</p> <p>25 I assume that this is something</p>

55 (Pages 214 to 217)

Christian Merlo, M.D., MPH

Page 218	Page 220
<p>1 that you read before you cited it in your 2 report? 3 MR. LOCKE: Objection. 4 THE WITNESS: So this -- 5 this -- 6 QUESTIONS BY MR. TISI: 7 Q. Actually, it's a very simple 8 question: I assume you read it before citing 9 it? 10 A. I did look at this website from 11 the CDC. This definition actually comes out 12 of several textbooks, and the reference from 13 those -- 14 Q. Doctor, I didn't ask you that 15 question. I asked you whether you -- 16 A. I'm giving you an answer. 17 Q. I just asked you whether you 18 read it. 19 A. And so I'm giving you an 20 answer. 21 Where I found this definition 22 was in several textbooks. When I looked back 23 to the reference, it referenced this lesson. 24 Did I read this entire thing? 25 I don't recall. I know that I did look this</p>	<p>1 action based on this science and causal 2 reasoning." 3 Do you see that? 4 A. I do see that. 5 Q. Okay. 6 A. And that's why I put this 7 definition in -- 8 Q. Okay. 9 A. -- when I was defining 10 epidemiology, because I said that it's "the 11 study of the distribution and determinants of 12 health-related states or events in specific 13 populations and the application of this study 14 to control health problems." 15 Q. Right. 16 A. And that's what I was looking 17 for, is a definition -- 18 Q. And it also -- and it also uses 19 the word "causal reasoning." 20 A. If I could just finish -- 21 Q. Well, I understand, but -- 22 A. -- because I'm giving you an 23 answer. 24 Q. You're not -- I asked you about 25 a particular sentence. Okay? I didn't ask</p>
Page 219	Page 221
<p>1 up on the CD's website -- CDC's website and 2 did take this definition from one or the 3 entirety of those -- of those references, and 4 I don't specifically remember where. 5 Q. Okay. You cited it, and so 6 let's go through it. Okay? 7 On page 1 it says, 8 "Epidemiology is just -- is not just a 9 research activity but an integral component 10 of public health providing the foundation for 11 directing practical and appropriate public 12 health action based upon this science and 13 causal reasoning." 14 MS. MILLER: Do you know where 15 he is? 16 THE WITNESS: I'm sorry, where 17 are you? 18 QUESTIONS BY MR. TISI: 19 Q. The last sentence on the first 20 page. 21 I'll read it again. 22 "Epidemiology is not just a research activity 23 but an integral component of public health 24 providing the foundation for directing 25 practical and appropriate public health</p>	<p>1 you why you used it. I didn't ask you -- you 2 need to -- I'm perfectly happy to let you 3 answer the question, but I'm also -- it's 4 also important that you listen to my 5 question. Okay? 6 My question is: Do you agree 7 with the statement that I just read? 8 I didn't ask you why. I didn't 9 ask how. I didn't ask you what you did to do 10 get there. I simply asked you whether you 11 agree with it. 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 Assuming that was a question 15 and not a speech. I'm -- 16 MR. TISI: It was a speech, 17 actually. 18 MS. MILLER: Oh. I'm objecting 19 to it as a speech. 20 MR. TISI: Fine. 21 QUESTIONS BY MR. TISI: 22 Q. So now I'm going to ask you the 23 question. 24 Do you agree with the sentence 25 that is in the article that you cited?</p>

56 (Pages 218 to 221)

Christian Merlo, M.D., MPH

Page 222	Page 224
<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: I would like to</p> <p>3 preface this by saying I am listening</p> <p>4 to your questions.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Okay. So I'm going to ask you</p> <p>7 to listen closer because the answers are not</p> <p>8 answering my question.</p> <p>9 So now let me ask you this</p> <p>10 question --</p> <p>11 MR. LOCKE: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. -- again, and it's a very</p> <p>14 simple one.</p> <p>15 Do you agree with the following</p> <p>16 statement, quote, "Epidemiology is not just a</p> <p>17 research activity but an integral component</p> <p>18 of public health, providing the foundation</p> <p>19 for directing practical and appropriate</p> <p>20 public health action based on this science</p> <p>21 and causal reasoning, close quote."</p> <p>22 Do you agree with that?</p> <p>23 A. It's a statement that's in</p> <p>24 this -- off the website.</p> <p>25 Q. And do you agree with it?</p>	<p>1 epidemiologist uses the scientific methods of</p> <p>2 descriptive and analytic epidemiology as well</p> <p>3 as experience, epidemiologic judgment and</p> <p>4 understanding of local conditions in</p> <p>5 diagnosing the health of a community and</p> <p>6 proposing appropriate practical and</p> <p>7 acceptable public health interventions to</p> <p>8 control and prevent disease in a community."</p> <p>9 First of all, did I read that</p> <p>10 right?</p> <p>11 A. You did read that correctly off</p> <p>12 the page.</p> <p>13 Q. Does it use the word -- does it</p> <p>14 make the statement that it -- that</p> <p>15 epidemiologists use scientific methods of</p> <p>16 descriptive and analytic epidemiology as well</p> <p>17 as experience and epidemiologic judgment?</p> <p>18 Does it not say that?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It says,</p> <p>21 "Similarly, the epidemiologist uses</p> <p>22 the scientific methods of descriptive</p> <p>23 and analytic epidemiology as well as</p> <p>24 experience, epidemiologic judgment and</p> <p>25 understanding of local conditions in</p>
Page 223	Page 225
<p>1 A. I mean, there's so many aspects</p> <p>2 to that statement --</p> <p>3 Q. I understand.</p> <p>4 A. -- that make it difficult to</p> <p>5 agree or disagree with. It depends. It --</p> <p>6 Q. Okay.</p> <p>7 A. I didn't write it, so I --</p> <p>8 Q. Now let's go to the end where</p> <p>9 it says, "Application" on the last page</p> <p>10 before the summary.</p> <p>11 Application. Do you see the</p> <p>12 paragraph? Let's see if we can read it</p> <p>13 together.</p> <p>14 "Epidemiology is not just the</p> <p>15 study of," in quotes, "public health in a</p> <p>16 population. It also involves applying the</p> <p>17 knowledge gained by the studies to</p> <p>18 community-based practice. Like the practice</p> <p>19 of medicine, the practice of epidemiology is</p> <p>20 both a science and an art. To make a proper</p> <p>21 diagnosis and to prescribe appropriate</p> <p>22 treatment for a patient, the clinician</p> <p>23 combines medical, scientific knowledge with</p> <p>24 experience, clinical judgment and</p> <p>25 understanding of the patient. Similarly, the</p>	<p>1 diagnosing the health of a community</p> <p>2 and proposing appropriate practical</p> <p>3 and acceptable public health</p> <p>4 interventions to control and prevent</p> <p>5 disease in the community."</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Do you agree with it?</p> <p>8 A. I mean, in general, that seems</p> <p>9 like a statement that -- that's why we use</p> <p>10 epidemiology.</p> <p>11 Q. Okay.</p> <p>12 A. I didn't write this. There's</p> <p>13 no reference there. There's -- this is a</p> <p>14 very, very general statement.</p> <p>15 Q. Okay. I agree.</p> <p>16 But you cited this particular</p> <p>17 document in your report, and I'm asking you</p> <p>18 about it.</p> <p>19 In fact, you make a lot of</p> <p>20 statements in your report that aren't cited</p> <p>21 either, right?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: You asked several</p> <p>24 questions there.</p> <p>25</p>

57 (Pages 222 to 225)

Christian Merlo, M.D., MPH

Page 226	Page 228
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, okay. You make a lot of</p> <p>3 statements in your report that aren't cited</p> <p>4 either, don't you?</p> <p>5 We just talked about the</p> <p>6 statistical significance paragraph, the one</p> <p>7 that's important to note. There was not a</p> <p>8 citation there either, right?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: In that instance</p> <p>12 there was not a citation.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Okay. So the fact that there's</p> <p>15 no citation, does that make your -- the</p> <p>16 opinion you express in your report invalid?</p> <p>17 A. Not necessarily.</p> <p>18 Q. Okay. So --</p> <p>19 A. But --</p> <p>20 Q. I want to ask you about this</p> <p>21 statement.</p> <p>22 A. I --</p> <p>23 Q. Well, I want to ask you about</p> <p>24 this statement. You answered my question,</p> <p>25 saying that there's no --</p>	<p>1 epidemiology.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Understood. I get it. I get</p> <p>4 it.</p> <p>5 Now I'm asking you: In the</p> <p>6 document that you cited is another statement.</p> <p>7 Do you agree with it or not agree with it?</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. And if you don't agree with it,</p> <p>11 I want to know why. And if you do agree with</p> <p>12 it, I'm fine with it.</p> <p>13 MS. MILLER: Okay. So what's</p> <p>14 the question? Because I --</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you agree with it, or do you</p> <p>17 don't agree with it?</p> <p>18 MS. MILLER: Objection. Asked</p> <p>19 and answered.</p> <p>20 THE WITNESS: I think in</p> <p>21 general -- it's such a general</p> <p>22 statement that it depends. It depends</p> <p>23 on what we're talking about. It</p> <p>24 depends on what the study is doing.</p> <p>25 It's so general that there's no</p>
Page 227	Page 229
<p>1 A. No, I didn't. No, I didn't. I</p> <p>2 didn't finish. And --</p> <p>3 Q. Doctor --</p> <p>4 A. And --</p> <p>5 Q. Do you agree or disagree --</p> <p>6 MS. MILLER: He's literally in</p> <p>7 the middle of a word --</p> <p>8 THE WITNESS: And I would</p> <p>9 appreciate it if you would stop</p> <p>10 interrupting. Just let me finish.</p> <p>11 It's fine.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Fine. I would appreciate if</p> <p>14 you answer my question.</p> <p>15 Do you agree or disagree with</p> <p>16 the application paragraph in this document?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: It's not</p> <p>19 something to agree or disagree with.</p> <p>20 It's from a website that is online.</p> <p>21 I cited this to give a</p> <p>22 definition of what epidemiology is.</p> <p>23 It doesn't mean I agree or disagree</p> <p>24 with the entire thing. I used this as</p> <p>25 a way to get a definition for</p>	<p>1 way to agree or disagree with it.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. Well, I guess the CDC</p> <p>4 would be happy to know that.</p> <p>5 MR. LOCKE: Objection.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Let's move on to the discussion</p> <p>8 on paragraph -- page 33, footnote 75. And we</p> <p>9 talked about this very briefly, the IPPHS</p> <p>10 study on the primary pulmonary hypertension?</p> <p>11 A. Are you referring to my report?</p> <p>12 Q. Yes.</p> <p>13 A. Okay.</p> <p>14 Q. Page 33?</p> <p>15 A. 33.</p> <p>16 Q. Footnote 75.</p> <p>17 In the footnote you cite a</p> <p>18 study by Abenhaim, appetite suppressants and</p> <p>19 the risk of primary pulmonary hypertension in</p> <p>20 1996, for the proposition for -- where you're</p> <p>21 discussing strength of association, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. All right. And I thought that</p> <p>24 was an interesting example that you took, and</p> <p>25 I want to ask you some questions about that.</p>

58 (Pages 226 to 229)

Christian Merlo, M.D., MPH

Page 230	Page 232
<p>1 You mentioned before that you</p> <p>2 believe that anorexigens, fenfluramine and</p> <p>3 dexfenfluramine, can cause primary pulmonary</p> <p>4 hypertension, correct?</p> <p>5 You remember that testimony?</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MS. MILLER: Objection. I</p> <p>8 don't think that characterizes his</p> <p>9 testimony accurately.</p> <p>10 THE WITNESS: As a clinician,</p> <p>11 when I see patients who have been</p> <p>12 diagnosed with pulmonary hypertension,</p> <p>13 asking about anorexigens is part of my</p> <p>14 clinical evaluation because of studies</p> <p>15 that have looked into the association.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. So and I think you</p> <p>18 testified before, and the record will reflect</p> <p>19 what you testified to, but I think you did</p> <p>20 testify before that you believed on balance</p> <p>21 that there is cause and effect there. But</p> <p>22 the record will be what the record is.</p> <p>23 Let me ask you this: Are you</p> <p>24 aware -- first of all, this is a case-control</p> <p>25 study, correct?</p>	<p>1 THE WITNESS: No, we'd have to</p> <p>2 look back through the records.</p> <p>3 (Merlo Exhibit 25 marked for</p> <p>4 identification.)</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. My question to you is this:</p> <p>7 Did you do the same kind of rigorous analysis</p> <p>8 of this study that you did of the studies</p> <p>9 involving talc?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: My -- the reason</p> <p>12 that I included this study in my</p> <p>13 report was because -- was to -- was to</p> <p>14 highlight a strength of association.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I understand.</p> <p>17 A. And an odds ratio of 6.3 that</p> <p>18 actually increases to -- well, I could look</p> <p>19 here -- to 23.1 when the drugs were used for</p> <p>20 more than three months is a high strength of</p> <p>21 association.</p> <p>22 Q. Okay.</p> <p>23 A. So the reason that I included</p> <p>24 it was to make the point that it is very,</p> <p>25 very, very difficult, almost impossible, to</p>
Page 231	Page 233
<p>1 A. It is a case-control study.</p> <p>2 Q. Subject to all the same biases</p> <p>3 that you discussed with respect to the</p> <p>4 case-control studies in this case, correct?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: So some of the</p> <p>7 biases. But we have to remember that</p> <p>8 this is a medication study, and so the</p> <p>9 medications can be looked at in the</p> <p>10 record, they can be looked as whether</p> <p>11 or not someone's been prescribed them.</p> <p>12 So it is a little bit different</p> <p>13 there in that this is not just</p> <p>14 recalling back, this is -- you can</p> <p>15 look to see whether or not people were</p> <p>16 on medications.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Do you know whether they did</p> <p>19 that?</p> <p>20 A. I'd have to read the article</p> <p>21 again.</p> <p>22 Q. Okay. Well, you're just</p> <p>23 speculating right now as you're talking?</p> <p>24 MR. LOCKE: Objection.</p> <p>25 MS. MILLER: Objection.</p>	<p>1 explain away an odds ratio of 23.1 by some</p> <p>2 other factor, bias or confounding.</p> <p>3 Q. It's funny because I was</p> <p>4 involved in the litigation involving that,</p> <p>5 and that's exactly what experts like you</p> <p>6 said.</p> <p>7 But we'll go back -- let me go</p> <p>8 back and ask you this question, Doctor.</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Do you know --</p> <p>13 MS. MILLER: Enough with the</p> <p>14 speeches. "Experts like you"? What</p> <p>15 does that even mean?</p> <p>16 MR. TISI: Experts like you,</p> <p>17 hired by the companies. Experts like</p> <p>18 you.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Let me ask you --</p> <p>21 MR. LOCKE: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Let me ask you --</p> <p>24 MS. SHARKO: Please behave the</p> <p>25 way you would in court.</p>

Christian Merlo, M.D., MPH

Page 234	Page 236
<p>1 THE WITNESS: So I've never 2 been hired by a company -- 3 QUESTIONS BY MR. TISI: 4 Q. Okay. 5 A. -- to evaluate primary 6 pulmonary hypertension drugs. So I would 7 appreciate you not labeling me as something 8 that I am not. 9 Q. Okay. So let me ask you this, 10 Doctor: Are you aware that there was no -- 11 first of all, are you aware there's no cohort 12 studies involving primary pulmonary 13 hypertension anorexigen use? 14 A. So I'm aware of cohort studies 15 that have followed patients with pulmonary 16 hypertension, but I'm not aware that they 17 looked at exposures over time in cohort 18 studies. 19 Q. Were you aware that there are 20 no other case-control studies; in fact, this 21 is the only one? 22 MR. LOCKE: Objection. 23 THE WITNESS: Again, I would 24 have to review the medical literature 25 to --</p>	<p>1 ratio for you, Dr. Merlo, to say you don't 2 need a second one, it's enough? 3 MS. MILLER: Objection. 4 MR. LOCKE: Objection. 5 THE WITNESS: So, again, I'm 6 going to say it depends. It depends 7 on not only the study design, but I 8 was going to finish with how the study 9 was conducted. But what plans were 10 taken to try to limit bias, what plans 11 were taken in the analysis to try to 12 adjust for potential confounding, and 13 what was done in the analysis. And 14 that -- it depends. It depends on all 15 those things. 16 QUESTIONS BY MR. TISI: 17 Q. Let's go to your report at the 18 end -- the summary paragraph, and we'll go 19 elsewhere. I want to address your opinions 20 about the so-called hierarchy of evidence. 21 A. Sure. 22 Q. On page 46. 23 A. 46, I got it. 24 MS. MILLER: I'm going to 25 object to that speech.</p>
Page 235	Page 237
<p>1 QUESTIONS BY MR. TISI: 2 Q. Would it surprise you? 3 A. I'm sorry? 4 Q. Would it surprise you to know 5 that this is not the -- that this is the only 6 one? 7 MS. MILLER: Objection. 8 THE WITNESS: Not necessarily, 9 and I'll tell you why. Because if you 10 have a study that suggests -- that has 11 an odds ratio of 6.3 that goes up to 12 23, as a researcher, I'm not sure 13 another study would need to be done. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. At what point -- what 16 would the odds ratio have to be before you 17 say, we don't need to do a second one? 18 MS. MILLER: Objection. 19 THE WITNESS: It depends. It 20 depends on the study design. It 21 depends on the -- 22 QUESTIONS BY MR. TISI: 23 Q. Say a case-control study, what 24 level would a case-control study have to be 25 in terms of a statistically significant odds</p>	<p>1 QUESTIONS BY MR. TISI: 2 Q. You say -- 3 MR. TISI: No speech. 4 5 QUESTIONS BY MR. TISI: 6 Q. You call it the hierarchy of 7 evidence, right? 8 A. What are you referring to? 9 Q. Okay. "In particular, 10 plaintiffs' experts ignored the hierarchy of 11 evidence in evaluating studies." 12 Do you see that? 13 A. I do see that sentence. 14 Q. Okay. 15 A. Or that partial sentence. 16 Q. I want to talk about that. 17 I take it that you believe that 18 there is a recognized hierarchy of evidence 19 with cohort studies having higher evidentiary 20 values and reliability than case-control 21 studies? 22 MS. MILLER: Objection. Asked 23 and answered before lunch. 24 THE WITNESS: So that's not my 25 belief. It's a belief in epidemiology</p>

60 (Pages 234 to 237)

Christian Merlo, M.D., MPH

Page 238	Page 240
<p>1 that there is a hierarchy of evidence.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. And you also believe</p> <p>4 that within case-control studies that</p> <p>5 hospital-based studies are more reliable than</p> <p>6 population-control studies?</p> <p>7 MS. MILLER: Objection.</p> <p>8 THE WITNESS: What are you</p> <p>9 referring to?</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I'm asking -- you say here --</p> <p>12 MS. MILLER: Can you tell us</p> <p>13 what page you're on?</p> <p>14 MR. TISI: 46.</p> <p>15 MS. MILLER: Thanks.</p> <p>16 Do you have your report?</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. In your report you talk about</p> <p>19 the merits of hospital-based studies</p> <p>20 versus -- which in your view showed no</p> <p>21 association, and the case-control studies,</p> <p>22 some of which showed an association, the</p> <p>23 population-based ones?</p> <p>24 MS. MILLER: Is that a</p> <p>25 question?</p>	<p>1 A. And the reason for that is that</p> <p>2 there's thought that when a hospital-based</p> <p>3 case-control study is done, cases and</p> <p>4 controls think about the past in the same</p> <p>5 amount; whereas when we have population-based</p> <p>6 case-control studies, there may be</p> <p>7 difference -- differences in recall between</p> <p>8 cases and controls. And that's the</p> <p>9 definition of recall bias.</p> <p>10 MR. TISI: Okay. I'm going to</p> <p>11 move to strike.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. My question was in terms of</p> <p>14 evidentiary value. Do you place</p> <p>15 hospital-based studies having more -- give</p> <p>16 them more weight as a study design than</p> <p>17 population-based case-control study designs?</p> <p>18 MR. LOCKE: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. For whatever reason. I don't</p> <p>21 care what the reason is now.</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: So I'll say it</p> <p>24 depends.</p> <p>25 QUESTIONS BY MR. TISI:</p>
Page 239	Page 241
<p>1 MR. TISI: Yes.</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: Can you -- can</p> <p>4 you ask that again? Because I didn't</p> <p>5 understand that was a question.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Let me ask you directly.</p> <p>8 In terms of reliability, do you</p> <p>9 think that hospital-based studies are more</p> <p>10 reliable than population-based case-control</p> <p>11 studies?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: I don't know if</p> <p>14 more reliable -- I don't know if</p> <p>15 "reliable" is the right term. It's</p> <p>16 not a term we use in evaluating the</p> <p>17 literature.</p> <p>18 But there is some suggestion</p> <p>19 that hospital-based case-control</p> <p>20 studies might be less susceptible to</p> <p>21 recall bias, and recall bias is a</p> <p>22 tremendous limitation in case-control</p> <p>23 studies of all kinds.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Okay.</p>	<p>1 Q. Okay.</p> <p>2 A. And it depends on the -- how</p> <p>3 the study is put together. It depends on</p> <p>4 what the study investigators used to tried to</p> <p>5 limit bias and what the study investigators</p> <p>6 tried to use to limit confounding.</p> <p>7 If -- a poorly designed</p> <p>8 hospital-based study may not be as good as a</p> <p>9 very well-designed population-based study and</p> <p>10 vice versa.</p> <p>11 Q. In terms of -- I'm sorry.</p> <p>12 A. But if we're talking about</p> <p>13 serious limitations in case-control studies,</p> <p>14 recall bias is one of them.</p> <p>15 And it's an accepted thought</p> <p>16 that recall bias is less in hospital-based</p> <p>17 case-control studies when compared to</p> <p>18 population-based studies.</p> <p>19 Q. What's your citation for that?</p> <p>20 A. I would have to look through.</p> <p>21 I know I talked about it in my report, but I</p> <p>22 have to -- if you give me a couple seconds,</p> <p>23 I'll look through that.</p> <p>24 MS. MILLER: Do you know what</p> <p>25 page it's on, Counsel?</p>

61 (Pages 238 to 241)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 242</p> <p>1 MR. TISI: Nope.</p> <p>2 MS. MILLER: I do.</p> <p>3 MR. TISI: Good for you.</p> <p>4 MS. MILLER: May I say that to</p> <p>5 cut to the chase?</p> <p>6 MR. TISI: No, I don't want --</p> <p>7 MS. MILLER: You want him to</p> <p>8 read through every page? Okay.</p> <p>9 MR. TISI: I don't want him to</p> <p>10 read every page, but I don't want you</p> <p>11 to coach your witness. Because I</p> <p>12 noticed before that you were circling</p> <p>13 things while he was looking at it, so</p> <p>14 I don't want to do it anymore.</p> <p>15 MR. LOCKE: Objection.</p> <p>16 MS. SHARKO: That's really</p> <p>17 inappropriate --</p> <p>18 MR. TISI: I understand it's --</p> <p>19 MS. SHARKO: -- Mr. Tisi, and</p> <p>20 it's not true.</p> <p>21 MR. TISI: The video will</p> <p>22 demonstrate that it is true.</p> <p>23 MR. LOCKE: It's false. She</p> <p>24 was circling something on the left</p> <p>25 side away from the witness.</p>	<p style="text-align: right;">Page 244</p> <p>1 cases and controls are patients, for</p> <p>2 example, in hospitalized patients."</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Is there a citation to it?</p> <p>5 A. There is, Schultz and Grimes.</p> <p>6 Q. Okay.</p> <p>7 A. "Where the degree of thinking</p> <p>8 about a possible exposure outcome is likely</p> <p>9 to be at similar levels."</p> <p>10 Q. Okay. All right. So going</p> <p>11 back to the hierarchy of evidence concept --</p> <p>12 because you mentioned that several times</p> <p>13 throughout your report, true?</p> <p>14 A. You've asked me several times</p> <p>15 about it, and I have talked about the</p> <p>16 hierarchy evidence in my report.</p> <p>17 Q. Okay. Well, let's talk about</p> <p>18 the places where you do talk about it.</p> <p>19 You mentioned it in your</p> <p>20 conclusion. We talked about that.</p> <p>21 Can you go to page 27 of your</p> <p>22 report?</p> <p>23 A. Sure.</p> <p>24 Q. At the very bottom of the page</p> <p>25 it says, "While cohort studies have their own</p>
<p style="text-align: right;">Page 243</p> <p>1 MR. TISI: Okay.</p> <p>2 MS. MILLER: To show to Susan.</p> <p>3 MS. SHARKO: With her computer</p> <p>4 open between Ms. Miller and the</p> <p>5 witness.</p> <p>6 MR. TISI: Well, I was accused</p> <p>7 before of kicking under the table,</p> <p>8 which I thought was absolutely</p> <p>9 inappropriate.</p> <p>10 MS. SHARKO: We understand</p> <p>11 that.</p> <p>12 MR. TISI: And incorrect.</p> <p>13 MS. SHARKO: You've mentioned</p> <p>14 that a number of times.</p> <p>15 MR. TISI: And incorrect. And</p> <p>16 incorrect and wrong and</p> <p>17 unprofessional. We're sitting at a</p> <p>18 conference table.</p> <p>19 MS. SHARKO: All right. So</p> <p>20 let's have a truce on the personal</p> <p>21 attacks and just take your deposition.</p> <p>22 MR. TISI: Perfect. Perfect.</p> <p>23 THE WITNESS: So on page 6, the</p> <p>24 last paragraph I say, "Recall bias is</p> <p>25 often less likely to occur when both</p>	<p style="text-align: right;">Page 245</p> <p>1 limitations like any other study design, the</p> <p>2 focused criticism of cohort studies by</p> <p>3 plaintiffs' epidemiologists, even though they</p> <p>4 generally are considered more reliable than</p> <p>5 case-control studies, suggesting a biased</p> <p>6 approach to their analysis."</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Okay. First of all, that's</p> <p>10 another example where you accused our experts</p> <p>11 of being biased, correct?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: I didn't accuse</p> <p>15 anything. I'm suggesting.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. You're suggesting.</p> <p>18 Do you believe that they used a</p> <p>19 biased methodology?</p> <p>20 A. I'm sorry.</p> <p>21 Q. Did you believe that they used</p> <p>22 a biased methodology?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: What I say here</p> <p>25 is "even though they're generally</p>

Christian Merlo, M.D., MPH

Page 246	Page 248
<p>1 considered more reliable than</p> <p>2 case-control studies suggests a biased</p> <p>3 approach to their analysis."</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Do you believe that they did?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I'm just going to</p> <p>8 read what I said.</p> <p>9 MS. MILLER: Asked and</p> <p>10 answered.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. I understand you read what you</p> <p>13 said. This is my opportunity to ask you</p> <p>14 questions about what you wrote. I can read</p> <p>15 what you said, too.</p> <p>16 Okay. So my question to you</p> <p>17 is: Do you believe that they used a biased</p> <p>18 approach --</p> <p>19 MS. MILLER: Objection.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. -- to their analysis?</p> <p>22 A. What I'm saying is that --</p> <p>23 Q. I'm not asking what you said.</p> <p>24 I'm asking what your opinion is now, Doctor.</p> <p>25 Is your opinion, if I close</p>	<p>1 generally accepted that they are more</p> <p>2 reliable than case-control studies," meaning</p> <p>3 cohort studies, true?</p> <p>4 MR. LOCKE: Objection.</p> <p>5 THE WITNESS: Can you state</p> <p>6 that as a question?</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Yes.</p> <p>9 Do you state that cohort</p> <p>10 studies here are more reliable than</p> <p>11 case-control studies?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: So it depends.</p> <p>14 In general, cohort studies, as I</p> <p>15 talked about earlier, when performed</p> <p>16 appropriate -- when designed</p> <p>17 appropriately, when performed</p> <p>18 appropriately, when analyzed</p> <p>19 appropriately, do fall higher up on</p> <p>20 the hierarchy of evidence when</p> <p>21 compared to case-control studies.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. On page 35, you have a whole</p> <p>24 section about the disregard of hierarchy of</p> <p>25 evidence.</p>
Page 247	Page 249
<p>1 this book and we don't read what you said,</p> <p>2 I'm asking you, do you think that they used a</p> <p>3 biased approach in looking at the</p> <p>4 case-control studies and the cohort studies?</p> <p>5 MS. MILLER: He was in the</p> <p>6 middle of answering, and you</p> <p>7 interrupted him to ask the question --</p> <p>8 MR. TISI: No, he was about to</p> <p>9 read me what -- this is what I said.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. I'm asking you what your</p> <p>12 opinion is.</p> <p>13 A. And my opinion is what I said.</p> <p>14 Q. Okay.</p> <p>15 A. And I'll say again.</p> <p>16 Q. No, you don't need read it</p> <p>17 again. If your opinion is limited to what it</p> <p>18 says here, then that's fine.</p> <p>19 Do you believe -- do you have</p> <p>20 any reason to know that they used -- well,</p> <p>21 strike that. Strike that. We'll let it</p> <p>22 stand.</p> <p>23 Before you discussed the state</p> <p>24 of mind of our experts and their sloppiness,</p> <p>25 their bias approach, you state, "It is</p>	<p>1 Do you see that?</p> <p>2 A. I do see the disregard for</p> <p>3 hierarchy of evidence.</p> <p>4 Q. And you're referring, again, to</p> <p>5 the methodologic flaw of plaintiffs' experts,</p> <p>6 which is the main Section 8 above, correct?</p> <p>7 A. Can you show me what you're</p> <p>8 referring to?</p> <p>9 Q. Yeah.</p> <p>10 Roman Numeral VIII is</p> <p>11 Methodologic Flaws of Plaintiffs' Experts'</p> <p>12 Epidemiology-Based Opinions. That's the</p> <p>13 title of this section?</p> <p>14 A. That's correct.</p> <p>15 Q. And the first criticism you</p> <p>16 have here is disregard for hierarchy of</p> <p>17 evidence, correct?</p> <p>18 A. I see that, disregard for</p> <p>19 hierarchy of evidence.</p> <p>20 Q. Are you saying that the</p> <p>21 plaintiffs' experts disregarded the hierarchy</p> <p>22 of evidence?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: In general, in</p> <p>25 comparing cohort studies to</p>

63 (Pages 246 to 249)

Christian Merlo, M.D., MPH

Page 250	Page 252
<p>1 case-control studies, they're just not 2 equal. I mean, cohort studies are 3 following subjects -- 4 QUESTIONS BY MR. TISI: 5 Q. Wasn't what I asked. So, 6 Doctor, sorry. I wasn't asking your opinion 7 about case control and cohort. 8 I'm asking you: Did the 9 plaintiffs' experts -- not what your views 10 are. Did, in your opinion, plaintiffs' 11 experts disregard the hierarchy of evidence? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 THE WITNESS: So -- and I'll 15 say that in general the hierarchy of 16 evidence does place cohort studies 17 above the case-control studies. And 18 to treat those studies equally in 19 looking at the body of evidence would 20 be disregarding the hierarchy of 21 evidence. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. And you say, "The 24 hierarchy of evidence is well-established in 25 the scientific community." And that's where</p>	<p>1 National Health Medical Research Council is? 2 MR. LOCKE: Objection. 3 THE WITNESS: I do not know who 4 the National Health and Medical 5 Research Council are. 6 QUESTIONS BY MR. TISI: 7 Q. Did you get this document from 8 the defense lawyers or did you find it on 9 your own? 10 A. I found this myself. 11 Q. Okay. Without -- but you don't 12 know who these people are? 13 A. I don't know who a lot of 14 people are that publish things. 15 Q. Well, you don't know what this 16 organization is, do you? 17 A. No, I don't. 18 Q. Okay. So -- but you say 19 here -- the only thing you cite for that is 20 this Australian document. 21 Can you tell me why you didn't 22 go to any of the textbooks that you use at 23 Hopkins to cite this well-established 24 principle? 25 A. No.</p>
Page 251	Page 253
<p>1 you cite the National Health and Research 2 Council. 3 And that's that Australian 4 white paper that we talked about before, 5 right? 6 MS. MILLER: Objection. 7 THE WITNESS: I'd have to look 8 at it. 9 (Merlo Exhibit 26 marked for 10 identification.) 11 QUESTIONS BY MR. TISI: 12 Q. Okay. We'll find it. 13 I'll attach this as Exhibit 14 Number 26. This is the paper to which you 15 were referring. 16 A. Yeah, I don't have this 17 memorized, the entirety. 18 Q. I'm not asking you about it. 19 I'm just asking if this is the document you 20 referenced to in your footnote. 21 A. This looks like it. 22 Q. Okay. Before when I asked you 23 about Health Canada, you said you didn't even 24 know who they were. 25 Do you know who the Australian</p>	<p>1 MR. LOCKE: Objection. 2 THE WITNESS: I mean, I could 3 have gone to textbooks, but I didn't. 4 QUESTIONS BY MR. TISI: 5 Q. Well, we will. 6 A. I looked things up. 7 Q. You call this a fundamental 8 principle of epidemiology, if you go to 9 page 46. First sentence, second paragraph of 10 your conclusions. 11 A. The first sentence of the 12 second paragraph? 13 Q. Uh-huh. 14 A. And what was the question? 15 Q. You call it a fundamental 16 principle of epidemiology, right? 17 A. The first sentence of the 18 second paragraph says, "The methodologies 19 used by plaintiffs' experts ignore 20 fundamental principles of epidemiology." 21 Q. In particular, plaintiffs' 22 experts ignore the hierarchy of evidence. 23 A. Yes. 24 Q. That's what you're referring 25 to?</p>

64 (Pages 250 to 253)

Christian Merlo, M.D., MPH

Page 254	Page 256
<p>1 A. Yes.</p> <p>2 Q. Okay. So in your whole report,</p> <p>3 the only thing you cited was this Australian</p> <p>4 document, which we've marked as Exhibit</p> <p>5 Number 26, on this fundamental principle,</p> <p>6 right?</p> <p>7 MR. LOCKE: Objection.</p> <p>8 MS. MILLER: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Because I don't see any other</p> <p>11 citation in any other place other than this</p> <p>12 Australian document from the organization you</p> <p>13 know who they are.</p> <p>14 A. That's the citation I used. I</p> <p>15 teach about this in class. I've been taught</p> <p>16 about it in class.</p> <p>17 Q. Okay.</p> <p>18 A. You're welcome to take my class</p> <p>19 and see the slides.</p> <p>20 Q. I think I'm gonna.</p> <p>21 Putting aside your concern</p> <p>22 about how the experts weighed the talc</p> <p>23 studies, you believe that the cohort design</p> <p>24 is the best for measuring ovarian cancer?</p> <p>25 MS. MILLER: Objection.</p>	<p>1 A. So I wasn't -- I wasn't</p> <p>2 involved in any of the design of the cohort</p> <p>3 studies, but one of the beauties of a cohort</p> <p>4 study is you actually don't need that.</p> <p>5 Q. Okay.</p> <p>6 A. And what you do is you follow</p> <p>7 patients over time, and sometimes things come</p> <p>8 up. And you might add a questionnaire in and</p> <p>9 then follow because you have a large group of</p> <p>10 people that you're following over time. You</p> <p>11 have a time zero with some measurement, and</p> <p>12 then an outcome that develops. And that's --</p> <p>13 that's the purpose of a cohort study --</p> <p>14 Q. How long --</p> <p>15 A. -- that you don't need to have</p> <p>16 one hypothesis.</p> <p>17 Q. How large would a study -- have</p> <p>18 you done any power calculations to determine</p> <p>19 how large a study would have to be in order</p> <p>20 to accurately collect information that would</p> <p>21 be useful in determining where there's</p> <p>22 association?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I don't</p> <p>25 understand your question. It doesn't</p>
Page 255	Page 257
<p>1 THE WITNESS: Again, it</p> <p>2 depends. It depends on the -- how the</p> <p>3 study is set up. It depends on</p> <p>4 what -- it depends on how long someone</p> <p>5 is followed. It depends on the study</p> <p>6 population being looked at. It</p> <p>7 depends on what potential bias was --</p> <p>8 tried to -- it depends on the</p> <p>9 investigators planning to try to limit</p> <p>10 bias. It depends on the plan to</p> <p>11 adjust for potential confounders.</p> <p>12 So it depends. It's too</p> <p>13 general to answer.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Do you know whether or not any</p> <p>16 of the cohort studies had, as one of its</p> <p>17 primary focuses at the initiation of this</p> <p>18 study, assessing whether or not talc causes</p> <p>19 ovarian cancer?</p> <p>20 A. Can you ask that again?</p> <p>21 Q. Yes.</p> <p>22 Do you know whether or not one</p> <p>23 of the hypotheses that was considered at the</p> <p>24 inception of any of these cohort studies was</p> <p>25 that talc could cause ovarian cancer?</p>	<p>1 make sense.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. How large? How large would a</p> <p>4 study have to be?</p> <p>5 How many patients would have to</p> <p>6 be enrolled in a cohort study in order to get</p> <p>7 good information about whether or not talc is</p> <p>8 associated with ovarian cancer?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: So it depends.</p> <p>11 It depends on the study. It depends</p> <p>12 on the study population.</p> <p>13 If you're looking at younger</p> <p>14 women, it may take -- there may be --</p> <p>15 you may need a larger study</p> <p>16 population. If you're looking at</p> <p>17 women, say, in their 50s, you need a</p> <p>18 smaller population.</p> <p>19 It's all going to depend on</p> <p>20 the -- on the incidence of disease in</p> <p>21 the study population.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Did you look at that?</p> <p>24 A. I did.</p> <p>25 Q. Okay. How long would the study</p>

65 (Pages 254 to 257)

Christian Merlo, M.D., MPH

Page 258	Page 260
<p>1 have to be?</p> <p>2 A. It depends. It depends on</p> <p>3 the -- it depends on the population. It</p> <p>4 depends on what the incidence of disease in</p> <p>5 that population is.</p> <p>6 Q. And how long -- how long do you</p> <p>7 think it would have to be for a cohort study</p> <p>8 to detect ovarian cancer in women?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: Well, then I'm</p> <p>11 going to have to say it depends.</p> <p>12 Because in all women, that will --</p> <p>13 you'd need a very different number</p> <p>14 than in looking at, say, women who are</p> <p>15 55 to 65, because the incidence of</p> <p>16 disease is very different among</p> <p>17 different age populations.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Okay. So in women 55 to 65,</p> <p>20 did you independently assess how large a</p> <p>21 study would have to be?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I looked at power</p> <p>24 and sample size calculation under</p> <p>25 various assumptions, and those</p>	<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm not saying anything.</p> <p>3 What page are you looking at,</p> <p>4 Doctor?</p> <p>5 A. Well, this might not be -- 38.</p> <p>6 So 38, page 38, paragraph 1, where it says,</p> <p>7 "She relies on commentary by Narod, who</p> <p>8 states that the lack of significant overall</p> <p>9 association between ever talc use and ovarian</p> <p>10 cancer in the cohort studies may be due to</p> <p>11 the fact that despite the large size of the</p> <p>12 cohorts, the studies were not adequately</p> <p>13 powered to detect a relative risk of</p> <p>14 approximately 1.2."</p> <p>15 Q. Right.</p> <p>16 A. "But this commentary rests on</p> <p>17 sample size calculations with certain</p> <p>18 assumptions regarding the risk of ovarian</p> <p>19 cancer, including the same incidence rate</p> <p>20 issue that undermines Dr. McTiernan's</p> <p>21 critique. When the actual incidence rate of</p> <p>22 ovarian cancer in the cohort studies is taken</p> <p>23 into account, it decreases the study sample</p> <p>24 size needed to the sample size reported in</p> <p>25 the relevant cohort studies."</p>
Page 259	Page 261
<p>1 assumptions utilized the incidence of</p> <p>2 disease and the time to follow someone</p> <p>3 with varying times and varying</p> <p>4 incidence of disease.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. So how large would a study have</p> <p>7 to be in women age 50 to 55 to detect an</p> <p>8 association between talc and ovarian cancer?</p> <p>9 A. So I used 55 to 65 as an</p> <p>10 example just talking right here. I don't</p> <p>11 specifically remember right now the incidence</p> <p>12 of ovarian cancer in someone who is 55 to 60.</p> <p>13 I know that there are ranges,</p> <p>14 and those ranges are available on the</p> <p>15 Internet to look at incidence of disease</p> <p>16 based on age, and I used some of those ranges</p> <p>17 and some of those incidences.</p> <p>18 Q. Did you do calculations?</p> <p>19 A. I did calculations.</p> <p>20 Q. Where are they?</p> <p>21 A. They're in my report.</p> <p>22 Q. Where are they?</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: Give me a couple</p> <p>25 of seconds to find it.</p>	<p>1 Q. I understood. I read that.</p> <p>2 Where is your calculation for</p> <p>3 that?</p> <p>4 Did you -- it says when -- the</p> <p>5 last sentence says, "When the actual</p> <p>6 incidence rates of ovarian cancer in the</p> <p>7 cohort studies is taken into account, it</p> <p>8 decreases the study sample size."</p> <p>9 You did the calculation to make</p> <p>10 that conclusion, and I don't see it in your</p> <p>11 report.</p> <p>12 Can you tell me where it is?</p> <p>13 A. I did it on a computer, and it</p> <p>14 gave me a sample size that was similar to</p> <p>15 what was reported in the relative cohort</p> <p>16 studies when you use an incidence of ovarian</p> <p>17 cancer that's similar to the incidence rates</p> <p>18 of the population that was being studied.</p> <p>19 Q. You did it on a computer? It's</p> <p>20 not in your report.</p> <p>21 MS. MILLER: Yes, it is.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Well, tell me where it is.</p> <p>24 MR. TISI: I'm not asking</p> <p>25 counsel; I'm asking the witness.</p>

66 (Pages 258 to 261)

Christian Merlo, M.D., MPH

Page 262	Page 264
<p>1 MS. MILLER: Well, we can sit 2 and he can look for it, or I can tell 3 you where it is. 4 MR. TISI: It's funny how that 5 happens. When I ask him about a 6 specific sentence, you want him to 7 read the whole report. 8 MS. MILLER: No, that's not -- 9 no, that's exactly the opposite of 10 what I was saying. I said if you want 11 him to read the whole report, you can. 12 I also know where it is. 13 MR. TISI: No, that's -- it 14 depends on the question. 15 MS. SHARKO: Well, being nice 16 doesn't work, unfortunately. 17 MS. MILLER: Yeah, I'm trying 18 to be nice. That's the irony. 19 MR. TISI: You don't -- fine. 20 MS. MILLER: Do you want to 21 finish that sentence? 22 MR. TISI: Yes. 23 MS. MILLER: Go ahead. 24 MR. TISI: Your conduct during 25 the course of these depositions has</p>	<p>1 comparing participants exposed to talc to 2 participants not exposed to talc, I 3 calculated that the incidence of ovarian 4 cancer in the overall number of study 5 participants was sufficient to detect the 6 true risk of ovarian cancer of 1.25 with a 7 power of 99, 99 percent." 8 Q. So what would the number have 9 to be in order to be -- what was your number? 10 That's what I wanted to know. 11 A. I would have to look at my 12 computer again. I just know it's sufficient. 13 Q. Okay. But you didn't put in 14 your report what the number would have to be 15 to -- so I can't ask you that question, and 16 you don't know it here right now, do you? 17 MR. LOCKE: Objection. 18 THE WITNESS: The number is 19 over the number of participants 20 included in those studies. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. 23 A. And that means that there's 24 only a 1 percent chance of being incorrect -- 25 Q. Okay.</p>
Page 263	Page 265
<p>1 been anything but nice. 2 MR. LOCKE: Objection. 3 MR. TISI: If you really want 4 it to be put on the record, that's 5 what I was going to say. 6 To honor Susan's request, I was 7 going to forebear from that, but you 8 asked. 9 MS. SHARKO: Mr. Tisi, really. 10 THE WITNESS: So just give me a 11 couple seconds. I'll find it. 12 Okay. So I think I found 13 another instance where I described 14 that sample size would be adequate. 15 QUESTIONS BY MR. TISI: 16 Q. Okay. Where is that? 17 A. It's at page 37. 18 Q. Which paragraph? 19 A. Third paragraph. 20 Q. Okay. 21 A. And then halfway down that 22 paragraph it says, "Specifically using the 23 Berge study meta-analysis of cohort studies, 24 which concluded that combined cohort studies 25 yielded no risk of ovarian cancer when</p>	<p>1 A. -- if, in fact, there is no 2 difference in folks who haven't been 3 exposed -- or unexposed to talcum powder. 4 Q. Now, getting back to the -- 5 this fundamental principle of epidemiology 6 that there's this hierarchy of evidence, you 7 know that the current view in epidemiology, 8 in fact, a view that's been for a while, has 9 been that case control and epidemiologic case 10 control and cohort studies are looked at 11 together -- 12 MR. LOCKE: Objection. 13 QUESTIONS BY MR. TISI: 14 Q. -- if they exist together, 15 right? 16 MS. MILLER: Objection. 17 THE WITNESS: I don't 18 understand the question. You have to 19 ask it again. 20 QUESTIONS BY MR. TISI: 21 Q. Well, let's look at the Gordis 22 textbook again. Exhibit Number 23. 23 Can you look at Exhibit 23 24 again, Doctor? 25 MS. MILLER: Is that the</p>

67 (Pages 262 to 265)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 266</p> <p>1 Chapter 14?</p> <p>2 MR. TISI: Yeah.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Can you go to page 256? You</p> <p>5 use it as an example -- 255, excuse me. Oh,</p> <p>6 I'm sorry. 257, please.</p> <p>7 He uses as an exam -- and feel</p> <p>8 free to look at if you wish. He uses an</p> <p>9 example, the process for using evidence in</p> <p>10 developing recommendations, effectiveness of</p> <p>11 prenatal interventions. He's giving a</p> <p>12 causation approach here.</p> <p>13 The top here is categorizing</p> <p>14 the evidence by quality and source, and</p> <p>15 stage 2 is using the guidelines of evidence</p> <p>16 of causal relationship, and those would be</p> <p>17 the Bradford Hill criteria.</p> <p>18 Do you see that?</p> <p>19 A. I see this table and I see a --</p> <p>20 something that says, stage 1, categorizing</p> <p>21 the evidence by the quality of its source.</p> <p>22 I see stage 2, guidelines with</p> <p>23 some -- what Dr. Gordis calls criteria, some</p> <p>24 of which are some Bradford Hill</p> <p>25 considerations.</p>	<p style="text-align: right;">Page 268</p> <p>1 is?</p> <p>2 A. No.</p> <p>3 Q. You don't know who he is?</p> <p>4 A. I have no idea.</p> <p>5 Q. Okay. Do you know he's written</p> <p>6 a textbook on epidemiology?</p> <p>7 A. I don't know his textbook, no.</p> <p>8 (Merlo Exhibit 27 marked for</p> <p>9 identification.)</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Okay. So I'm going to show you</p> <p>12 and ask whether you agree with it. It's a</p> <p>13 textbook on case-control studies.</p> <p>14 Chapter 8. Did you read -- by</p> <p>15 the way, did you read Dr. Ballman's</p> <p>16 testimony?</p> <p>17 A. I did.</p> <p>18 Q. You did.</p> <p>19 So you saw a discussion of</p> <p>20 Dr. Rothman, right?</p> <p>21 A. Yes, but I don't know who</p> <p>22 Dr. Rothman is.</p> <p>23 Q. Okay. Spent a lot of time</p> <p>24 talking about Dr. Rothman.</p> <p>25 Let me ask you this --</p>
<p style="text-align: right;">Page 267</p> <p>1 Q. Okay. Now, let's look at the</p> <p>2 quality of evidence, because that's what</p> <p>3 we're talking about here, right?</p> <p>4 Number 1 is trials, and we</p> <p>5 talked about those before. Those would be</p> <p>6 kind of the human experimental trials, the</p> <p>7 placebo-control kind of trials, right?</p> <p>8 A. Usually trials are either</p> <p>9 randomized, double-blinded, placebo-control</p> <p>10 trials, or randomized, not blinded, or</p> <p>11 nonrandomized but clinical trials where an</p> <p>12 intervention is done.</p> <p>13 Q. Okay. And the second category</p> <p>14 he has here is cohort or case-control</p> <p>15 studies.</p> <p>16 Do you see that?</p> <p>17 A. I do see that line that says</p> <p>18 "cohort or case-control studies."</p> <p>19 Q. He doesn't say cohort and then</p> <p>20 case-control studies, does he?</p> <p>21 A. He doesn't.</p> <p>22 Q. Okay.</p> <p>23 A. They're both observational</p> <p>24 studies.</p> <p>25 Q. Do you know who Kenneth Rothman</p>	<p style="text-align: right;">Page 269</p> <p>1 MS. MILLER: I'm sorry,</p> <p>2 Mr. Tisi, can we have copies as well?</p> <p>3 MR. TISI: Oh, I'm sorry. That</p> <p>4 was an error. Here you go.</p> <p>5 MS. MILLER: Thank you so much.</p> <p>6 MR. TISI: You're so welcome.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Second sentence in the</p> <p>9 textbook -- second paragraph. It's on --</p> <p>10 this is on -- this chapter is entitled</p> <p>11 "Case-Control Studies," right?</p> <p>12 A. This chapter, Chapter 8, called</p> <p>13 "Case-Control Studies."</p> <p>14 Q. The second paragraph begins</p> <p>15 with the sentence, "Conventional wisdom about</p> <p>16 case-control studies is that they do not</p> <p>17 yield estimates of effect that are valid</p> <p>18 measures obtained from cohort studies. This</p> <p>19 thinking may reflect common misunderstandings</p> <p>20 in the conceptualizing of case-control</p> <p>21 studies, which will be clarified later."</p> <p>22 Do you see that?</p> <p>23 A. I do see that.</p> <p>24 Q. Do you agree with that?</p> <p>25 MS. MILLER: Objecton.</p>

68 (Pages 266 to 269)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 270</p> <p>1 THE WITNESS: This is a very, 2 very, very vague statement. 3 QUESTIONS BY MR. TISI: 4 Q. Okay. 5 A. And I'm going to have to say it 6 depends. It depends on who's thinking about 7 it. It depends on the quality of the 8 case-control study. It depends on the 9 quality of the cohort study. It depends on 10 so many things that I can't even agree nor 11 disagree with it. 12 (Merlo Exhibit 28 marked for 13 identification.) 14 QUESTIONS BY MR. TISI: 15 Q. Okay. Let me show you another 16 article by Dr. Rothman, Exhibit Number 28. 17 This is a review article 18 entitled "Six Persistent Misconceptions." 19 Do you see that? 20 A. I do. 21 Q. Have you seen this before? 22 A. Yes. 23 Q. Okay. Can you read 24 misconception number 1? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 272</p> <p>1 that, Doctor? I mean, honestly, I'm pulling 2 up book chapters, published articles. You 3 pulled up a white paper from Australia. 4 How do I check and ask you, 5 other than your say-so, as to what the 6 general acceptance is in the -- in the 7 epidemiologic community, other than you just 8 saying it? 9 MS. MILLER: Objection. 10 MR. LOCKE: Objection. 11 THE WITNESS: You can take a 12 class in epidemiology. 13 QUESTIONS BY MR. TISI: 14 Q. I don't think I'm going to take 15 your class. 16 A. Well, I didn't say my class. 17 You can take any class. 18 Q. I'm reading the textbooks, and 19 they don't say what you say. 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 (Merlo Exhibit 29 marked for 23 identification.) 24 QUESTIONS BY MR. TISI: 25 Q. I'm going to show you another</p>
<p style="text-align: right;">Page 271</p> <p>1 THE WITNESS: Misconception 1, 2 "There is a hierarchy of study 3 designs. Randomized trials provide 4 the greatest validity, followed by 5 cohort studies, with case-control 6 studies being least reliable." 7 QUESTIONS BY MR. TISI: 8 Q. You are -- studying for your 9 support of this general -- this general 10 proposition, you're citing that Australian -- 11 that Australian white paper, right? 12 MR. LOCKE: Objection. 13 QUESTIONS BY MR. TISI: 14 Q. You didn't study any published 15 literature. You didn't cite textbooks, 16 published literature, nothing? 17 MR. LOCKE: Objection. 18 MS. MILLER: Objection. 19 THE WITNESS: I'm citing -- I'm 20 citing that article, but I'm also 21 referencing my experience in 22 epidemiology as well as the general 23 sense among epidemiologists today. 24 QUESTIONS BY MR. TISI: 25 Q. The general -- how do I check</p>	<p style="text-align: right;">Page 273</p> <p>1 one. This is Dr. Rothman who actually was, 2 unlike you, consulted to look at the talc 3 question back in 2000. 4 Almost 20 years ago, right? 5 I'm going to show you that 6 Exhibit Number 29. 7 MS. SHARKO: Can we please just 8 have questions instead of accusatory 9 speeches? 10 MR. TISI: I thought there was 11 only one objector here. 12 QUESTIONS BY MR. TISI: 13 Q. Doctor, I show you Exhibit 14 Number 28, which is entitled "Interpretation 15 of Epidemiologic Studies on Talc and Ovarian 16 Cancer." 17 Have you seen this before? 18 A. Yes. 19 Q. Okay. Have you been shown or 20 have you seen the section on exposure 21 misclassification on page 3? 22 A. I see the -- I see the 23 paragraph underneath exposure 24 misclassification. 25 Q. Now, just to put things in</p>

<p style="text-align: right;">Page 274</p> <p>1 context, this is November of 2000, this date</p> <p>2 of this report, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. This is some -- this is</p> <p>5 like halfway, if that, in the timeline of all</p> <p>6 the studies that have been conducted in this</p> <p>7 case from 1982 to 2016?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: It's November</p> <p>11 of 2000 --</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Right.</p> <p>14 A. -- and that's when it was</p> <p>15 published.</p> <p>16 Q. So what he's saying here, and</p> <p>17 I'm going to read it for the record, not all</p> <p>18 the study -- "nearly all the studies were</p> <p>19 case-control studies. It is commonly</p> <p>20 believed that the validity of case-control</p> <p>21 studies is worse than cohort studies, but</p> <p>22 this view is mistaken. The validity of the</p> <p>23 study depends on the specifics of the study</p> <p>24 design, the nature of the data and the nature</p> <p>25 of the hypothesis that the study addresses."</p>	<p style="text-align: right;">Page 276</p> <p>1 design, talked about the methodology used in</p> <p>2 the studies and the conclusions reached in</p> <p>3 the study, right? They went through every</p> <p>4 one of them.</p> <p>5 MS. MILLER: Objection.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 MR. TISI: True?</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: You'd have to be</p> <p>10 more specific --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Well, you reviewed them and you</p> <p>13 made the criticisms.</p> <p>14 So can you tell me one expert</p> <p>15 who -- both plaintiffs' experts who did not</p> <p>16 look at the study design for the</p> <p>17 case-controls and cohorts, who did not look</p> <p>18 at the methodology and who did not look at</p> <p>19 the results?</p> <p>20 MS. MILLER: Objection.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: You'd have to be</p> <p>23 more specific. If we look at the --</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. No, you'll have to be more</p>
<p style="text-align: right;">Page 275</p> <p>1 Do you see that?</p> <p>2 A. I do see that.</p> <p>3 Q. Do you agree with it or not?</p> <p>4 A. Well, I think I said earlier,</p> <p>5 and I've said it in my report, that the</p> <p>6 hierarchy of evidence is in general. And I</p> <p>7 said that a poorly designed or a poorly</p> <p>8 executed or a poorly analyzed cohort study</p> <p>9 may be less evident than a very, very</p> <p>10 well-designed case control.</p> <p>11 Q. So when -- I'm sorry.</p> <p>12 A. And the same thing for</p> <p>13 randomized control trials.</p> <p>14 But when looking at the</p> <p>15 different study designs, if properly</p> <p>16 designed, if properly conducted, if properly</p> <p>17 analyzed and if properly interpreted, a</p> <p>18 randomized control trial gives you higher</p> <p>19 evidence than a cohort, which gives you</p> <p>20 higher evidence than a case-control, which</p> <p>21 gives you higher evidence than a case series.</p> <p>22 Q. And you --</p> <p>23 A. In general.</p> <p>24 Q. And you saw that plaintiffs'</p> <p>25 experts, each one of them, talked about study</p>	<p style="text-align: right;">Page 277</p> <p>1 specific because you made some bald</p> <p>2 accusations here, and I really need you to be</p> <p>3 specific. I need you to tell me: Did</p> <p>4 plaintiffs' experts -- did plaintiffs'</p> <p>5 experts -- did they do or not do an analysis</p> <p>6 of each study?</p> <p>7 MS. MILLER: Objection.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: There were</p> <p>10 summaries of studies, but we'd have to</p> <p>11 go through each expert and go through</p> <p>12 the reports of each one of them to get</p> <p>13 specific about it.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. You disagree with the</p> <p>16 way in which they characterize them, but they</p> <p>17 just didn't simply list the studies, did</p> <p>18 they?</p> <p>19 MS. MILLER: Objection.</p> <p>20 MR. LOCKE: Objection.</p> <p>21 THE WITNESS: I never said I</p> <p>22 disagreed.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay.</p> <p>25 A. With whatever you're saying.</p>

Christian Merlo, M.D., MPH

Page 278	Page 280
<p>1 Q. Okay. All four studies --</p> <p>2 MS. MILLER: Do you want a</p> <p>3 break?</p> <p>4 MR. TISI: If -- he can tell me</p> <p>5 if he wants a break.</p> <p>6 THE WITNESS: I'm okay.</p> <p>7 MR. TISI: He just said he's</p> <p>8 okay.</p> <p>9 MS. MILLER: Do we have a new</p> <p>10 rule in depositions where lawyers</p> <p>11 can't ask for a break?</p> <p>12 MR. TISI: If you want to ask</p> <p>13 for a break, that's fine. If he's --</p> <p>14 you asked him whether he wants a</p> <p>15 break.</p> <p>16 MS. MILLER: This is just</p> <p>17 getting surreal, Susan.</p> <p>18 MR. TISI: It is totally</p> <p>19 getting surreal. You asked him</p> <p>20 whether he wants a break.</p> <p>21 Can you read that back? Can</p> <p>22 you read that back?</p> <p>23 MS. SHARKO: I thought -- are</p> <p>24 we really going to have this kind of</p> <p>25 meltdown over a break, Mr. Tisi?</p>	<p>1 2:00 p.m. We're going off the record.</p> <p>2 (Off the record at 2:00 p.m.)</p> <p>3 VIDEOGRAPHER: Okay. The time</p> <p>4 is 2:11 p.m., and we're back on the</p> <p>5 record.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Was the talc/ovarian cancer</p> <p>8 hypothesis prespecified in any of the cohort</p> <p>9 studies?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: I don't know.</p> <p>12 The cohort studies involving the</p> <p>13 Nurses' Health Study, for instance,</p> <p>14 added a questionnaire in 1982.</p> <p>15 And so if one added a</p> <p>16 questionnaire in 1982 asking about</p> <p>17 talc, at that point in the cohort</p> <p>18 study there may have been a hypothesis</p> <p>19 about that. That's why they added</p> <p>20 that -- that's why one might think</p> <p>21 that they added a questionnaire.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. You don't know that because the</p> <p>24 study doesn't say that, does it?</p> <p>25 MS. MILLER: Objection.</p>
Page 279	Page 281
<p>1 MR. TISI: I am totally okay</p> <p>2 with her taking a break if she says "I</p> <p>3 would like to take a break." But</p> <p>4 don't ask the witness whether he wants</p> <p>5 to take a break, because that suggests</p> <p>6 that he should take a break.</p> <p>7 MS. SHARKO: Seriously?</p> <p>8 MR. TISI: That's coaching.</p> <p>9 MS. SHARKO: That's not</p> <p>10 coaching, Mr. Tisi.</p> <p>11 MS. MILLER: Was there a</p> <p>12 question? Was there a question</p> <p>13 pending?</p> <p>14 MR. TISI: It's totally</p> <p>15 coaching.</p> <p>16 Did you need to take a break,</p> <p>17 or do you want to go forward?</p> <p>18 Do you want to take a break?</p> <p>19 MS. MILLER: I would like to</p> <p>20 take a break.</p> <p>21 MS. SHARKO: I want to take a</p> <p>22 break.</p> <p>23 MR. TISI: Perfect. All you</p> <p>24 have to do is ask.</p> <p>25 VIDEOGRAPHER: The time is</p>	<p>1 THE WITNESS: I'd have to</p> <p>2 review the study back -- to look at</p> <p>3 it. I don't have it memorized.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. How many times in each of these</p> <p>6 cohort studies -- what is the concept of</p> <p>7 exposure classification?</p> <p>8 A. Can you be more specific?</p> <p>9 Q. Yeah.</p> <p>10 What is exposure mis -- is that</p> <p>11 a term of art in epidemiology?</p> <p>12 A. Well, misclassification is a</p> <p>13 term. And you can have misclassification in</p> <p>14 both exposure and both in outcome if --</p> <p>15 Q. I'm asking you about exposure</p> <p>16 misclassification. Actually, I'm using the</p> <p>17 term that Dr. Rothman used.</p> <p>18 By the way, you know, Doctor,</p> <p>19 the journal American Epidemiologists?</p> <p>20 A. I don't.</p> <p>21 Q. Okay. Do you know -- have you</p> <p>22 ever heard of the Ken Rothman Award in</p> <p>23 epidemiology?</p> <p>24 A. I've never heard of that.</p> <p>25 Q. Okay. All right. So</p>

71 (Pages 278 to 281)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 282</p> <p>1 Dr. Rothman and his colleagues talk about</p> <p>2 exposure misclassification in Exhibit</p> <p>3 Number 29.</p> <p>4 Do you know what that concept</p> <p>5 is?</p> <p>6 A. And what page is that on again?</p> <p>7 Q. I'm just asking you what it is.</p> <p>8 I mean, it's in Exhibit 29 he uses the term.</p> <p>9 Do you know what it is?</p> <p>10 A. Well, you're referring to this.</p> <p>11 I haven't read this paragraph yet, but I do</p> <p>12 know what exposure misclassification is.</p> <p>13 Q. Then that's what I want. What</p> <p>14 is exposure misclassification?</p> <p>15 A. Misclassification involving an</p> <p>16 exposure is when either a study subject is</p> <p>17 classified as being exposed when they're not</p> <p>18 exposed or being classified as not exposed</p> <p>19 when they're exposed.</p> <p>20 Q. And exposure misclassification,</p> <p>21 generally speaking, will bias the results</p> <p>22 towards the null, correct?</p> <p>23 A. Not necessarily.</p> <p>24 Q. I didn't say necessarily. I</p> <p>25 said generally speaking.</p>	<p style="text-align: right;">Page 284</p> <p>1 think you said it's the one that biases</p> <p>2 toward the null -- is that a problem with</p> <p>3 cohort studies?</p> <p>4 A. Nondifferential --</p> <p>5 Q. Nondifferential?</p> <p>6 A. -- misclassification --</p> <p>7 Q. Yes.</p> <p>8 A. -- biases toward the null.</p> <p>9 Q. Right.</p> <p>10 Is that a recognized concern</p> <p>11 with cohort studies?</p> <p>12 A. So it depends. It depends if</p> <p>13 there's some reason to believe that those who</p> <p>14 are exposed actually are unexposed, and those</p> <p>15 that are unexposed are being labeled as</p> <p>16 exposed.</p> <p>17 Q. And in the cohort studies on</p> <p>18 talc, would it -- isn't it generally true</p> <p>19 across the cohort studies that women were</p> <p>20 asked about that talc exposure only once?</p> <p>21 A. I would have to review the</p> <p>22 articles again. I don't know that I</p> <p>23 specifically have that memorized.</p> <p>24 Q. Okay. If that were true, would</p> <p>25 there be a danger of exposure</p>
<p style="text-align: right;">Page 283</p> <p>1 Wouldn't that be the case?</p> <p>2 A. No, absolutely not.</p> <p>3 Q. Okay.</p> <p>4 A. And I'll tell you why.</p> <p>5 Q. Please.</p> <p>6 A. Because there are two different</p> <p>7 types of misclassification. One is</p> <p>8 traditionally referred to as differential</p> <p>9 misclassification, and one is traditionally</p> <p>10 referred to as nondifferential</p> <p>11 misclassification.</p> <p>12 Nondifferential</p> <p>13 misclassification can bias the study results</p> <p>14 to the null. Differential misclassification,</p> <p>15 such as that occurs with recall bias, can</p> <p>16 actually bias the result away from the</p> <p>17 null --</p> <p>18 Q. Okay.</p> <p>19 A. -- and give you an overinflated</p> <p>20 estimate of risk.</p> <p>21 Q. Is recall bias an aspect of</p> <p>22 exposure misclassification; do you think?</p> <p>23 A. Absolutely.</p> <p>24 Q. Okay. So exposure</p> <p>25 misclassification that is differential -- I</p>	<p style="text-align: right;">Page 285</p> <p>1 misclassification?</p> <p>2 A. Again, I think it depends. It</p> <p>3 depends on -- it depends on the</p> <p>4 questionnaire. It depends on the time</p> <p>5 between questionnaire and measurement of</p> <p>6 outcome. It depends on whether or not</p> <p>7 there's any aspect of asking about potential</p> <p>8 exposure in the past, and it depends a lot --</p> <p>9 it depends on a lot of things.</p> <p>10 Q. Did you review the Taher draft</p> <p>11 article meta-analysis?</p> <p>12 A. I did review Taher.</p> <p>13 Q. Do you know whether or not</p> <p>14 exposure misclassification was identified as</p> <p>15 a shortcoming in the cohort studies dealing</p> <p>16 with talc?</p> <p>17 A. I would have to look at the</p> <p>18 draft and see what you're referring to.</p> <p>19 Q. No, I'm not asking about the</p> <p>20 draft. I'm asking in the cohort studies</p> <p>21 themselves.</p> <p>22 A. I'm sorry?</p> <p>23 Q. Didn't the authors of the</p> <p>24 cohort studies identify weaknesses in their</p> <p>25 studies?</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 286</p> <p>1 MS. MILLER: Objection. 2 THE WITNESS: You'd have to be 3 more specific and see which -- what 4 study are we talking about? 5 QUESTIONS BY MR. TISI: 6 Q. Did they identify a concern 7 about a limitation being that there might be 8 recall -- excuse me, might be exposure 9 misclassification, nondifferential 10 misclassification? 11 MS. MILLER: Objection. 12 THE WITNESS: You'd have to 13 point me to the specific article that 14 you're referring to. 15 QUESTIONS BY MR. TISI: 16 Q. You don't know whether or not 17 the authors in any of those studies discussed 18 it? 19 A. There are so many articles 20 here, so many reports, a lot of paper, I 21 don't have things memorized. 22 Q. You -- 23 A. If there's certain -- something 24 that you want to ask me about the cohort 25 studies --</p>	<p style="text-align: right;">Page 288</p> <p>1 MS. MILLER: Objection. 2 MR. LOCKE: Objection. 3 THE WITNESS: I'm sorry? 4 QUESTIONS BY MR. TISI: 5 Q. When's the last time you read 6 your report before you came in here today? 7 A. I read it last night. 8 Q. Okay. 9 A. But again, there's a lot of 10 information here, and I don't have things 11 memorized. 12 Q. I agree. I agree. 13 So on page 24 and 25 you 14 discuss -- and 26 you discuss Gates, 15 Houghton, Gonzales and Gertig. I don't see 16 any discussion about the concern of 17 nondifferential misclassification bias. 18 A. Okay. 19 Q. Do you agree? 20 A. Do I agree with what? 21 Q. Did you discuss nondifferential 22 misclassification bias in your discussion of 23 the four cohort studies? 24 A. I discussed the potential for 25 nondifferential misclassification in</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. You put them in your report. 2 Did you address -- did you 3 address in your report, in your discussion of 4 the cohort studies, the concern about a 5 nondifferential misclassification of 6 exposure? 7 A. Can you ask that again? 8 Q. Yes. 9 In your report on your 10 discussion of the -- what you call the four 11 cohort studies, did you discuss the issue of 12 nondifferential misclassification of 13 exposure? 14 MS. MILLER: Objection. 15 THE WITNESS: I would have to 16 look through my report because I don't 17 have that memorized as well. 18 QUESTIONS BY MR. TISI: 19 Q. Well, your discussion of the 20 individual studies are on -- 21 A. Be happy to look at that. 22 Q. Yeah. On Houghton page 24 and 23 25. 24 I mean, I assume you read this 25 before you came in here today, right?</p>	<p style="text-align: right;">Page 289</p> <p>1 observational studies in my report. 2 Q. Did you discuss them in the 3 context of the talc studies? 4 A. I didn't. 5 Q. You know that that's a concern 6 that the plaintiffs' experts had when they 7 looked at the case -- excuse me, the cohort 8 studies, that women were asked only one time 9 whether they were exposed to talc and that 10 there was a potential for nondifferential 11 misclassification bias? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. Do you remember that? 16 A. You'd have to show me 17 specifically what you're referring to. 18 Q. You don't remember that that 19 was -- that was a primary focus of each one 20 of these experts? 21 MR. LOCKE: Objection. 22 MS. MILLER: Objection. 23 THE WITNESS: Again, you'd have 24 to show me the specifics because -- 25</p>

73 (Pages 286 to 289)

Christian Merlo, M.D., MPH

Page 290	Page 292
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Okay. But you don't address</p> <p>3 that in your report?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: I'm sorry?</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. You don't address that in your</p> <p>8 report with respect to the individual case --</p> <p>9 the individual cohort studies, do you?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: Nondifferential</p> <p>12 misclassification is a potential</p> <p>13 limitation of any observational study.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. I asked you whether you</p> <p>16 discussed it in the context of the cohort</p> <p>17 studies.</p> <p>18 MS. MILLER: Objection.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. The four cohort studies on</p> <p>21 talc, did you discuss -- did you even discuss</p> <p>22 that bias?</p> <p>23 I mean, you're sitting here</p> <p>24 telling our -- telling -- under oath telling</p> <p>25 our -- saying that our experts were, you</p>	<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. It is a general statement, and</p> <p>3 I suspect that -- I suspect that the judge</p> <p>4 might look at some of the words used in here</p> <p>5 and agree with me here.</p> <p>6 Pretty strong terms to say that</p> <p>7 somebody was using a -- conducting an</p> <p>8 analysis for the purpose of litigation and</p> <p>9 all the things that you've said. So -- but</p> <p>10 let's put that aside.</p> <p>11 MS. MILLER: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Let's put it aside. Put it</p> <p>14 aside.</p> <p>15 MS. MILLER: If that's a</p> <p>16 speech, I'm objecting to it. It</p> <p>17 mischaracterizes --</p> <p>18 MR. TISI: Put it aside.</p> <p>19 MS. MILLER: It</p> <p>20 mischaracterizes his report. If</p> <p>21 you're going to say it, then you're</p> <p>22 going to have to let me object to it.</p> <p>23 If you didn't want to say it --</p> <p>24 MR. TISI: Put it aside.</p> <p>25 MS. MILLER: -- then you</p>
Page 291	Page 293
<p>1 know, litigation-driven opinions, that they</p> <p>2 did all kinds of -- did all kinds of things</p> <p>3 that in your view were inappropriate for the</p> <p>4 purposes of litigation.</p> <p>5 I'm asking you: Did you look</p> <p>6 at the issue of recall -- excuse me, of</p> <p>7 nondifferential exposure misclassification</p> <p>8 with respect to the four cohort studies?</p> <p>9 MS. MILLER: Objection.</p> <p>10 MR. LOCKE: Objection.</p> <p>11 THE WITNESS: So I don't know</p> <p>12 what the first part of what you said</p> <p>13 was, whether or not that was a</p> <p>14 question.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Well, you are sitting here</p> <p>17 saying that they applied -- you are sitting</p> <p>18 here, and you've been -- made some very --</p> <p>19 used some very strong words in your report</p> <p>20 about the conduct of the plaintiffs' experts.</p> <p>21 Agreed?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: I mean, that's a</p> <p>24 general -- a very general statement,</p> <p>25 the conduct --</p>	<p>1 shouldn't have said it.</p> <p>2 MR. TISI: Put it aside.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. You didn't discuss -- one of</p> <p>5 your real criticisms is they did not</p> <p>6 account -- our experts did not account for</p> <p>7 recall bias in each of the case-control</p> <p>8 studies, true?</p> <p>9 A. I'm not saying that it wasn't</p> <p>10 accounted for. It's just a known limitation</p> <p>11 of case-control studies, absolutely.</p> <p>12 Q. Okay. Did our experts consider</p> <p>13 recall bias as part of looking at the</p> <p>14 talc-related case-control studies? Did they</p> <p>15 address the issue?</p> <p>16 MS. MILLER: Objection.</p> <p>17 THE WITNESS: Again, I think</p> <p>18 we'd have to look at each specific --</p> <p>19 each specific expert, and if there's a</p> <p>20 part in the expert report that you'd</p> <p>21 like to discuss, I'd like to have it</p> <p>22 in front of me. I don't have these --</p> <p>23 I don't have these --</p> <p>24 MR. TISI: You --</p> <p>25 THE WITNESS: I don't have</p>

74 (Pages 290 to 293)

Christian Merlo, M.D., MPH

Page 294	Page 296
<p>1 these memorized.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. You had an opportunity</p> <p>4 to write your report. There was no page</p> <p>5 limit on it. You could have written a</p> <p>6 thousand-page report if you'd wanted to.</p> <p>7 My question here is: You don't</p> <p>8 really -- you have criticisms of plaintiffs'</p> <p>9 experts generally, but you don't really</p> <p>10 address what they said about each individual</p> <p>11 study, do you?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Again, we'd have</p> <p>15 to go through each report --</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. You don't address. I'm not</p> <p>18 asking what they did. I'm asking: In your</p> <p>19 report, you do not address what each expert</p> <p>20 of the plaintiff said about each study, do</p> <p>21 you?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: I'm not sure what</p> <p>25 you're asking me.</p>	<p>1 exposure misclassification. You identified</p> <p>2 it as a potential weakness generally.</p> <p>3 Did you discuss that issue in</p> <p>4 connection with any one of the four cohort</p> <p>5 studies for talc?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: Misclassification</p> <p>8 is inherently a limitation in any</p> <p>9 study --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. And did you --</p> <p>12 A. -- case control or cohort</p> <p>13 studies. There are limitations inherent in</p> <p>14 the case-control studies that are in the</p> <p>15 literature. There are inherent limitations</p> <p>16 in the cohort studies that are out there.</p> <p>17 Q. Right.</p> <p>18 And just testified before that</p> <p>19 because of these things, you have to look at</p> <p>20 the design of each study individually, right?</p> <p>21 A better -- I think you said a</p> <p>22 well-designed cohort study is better than a</p> <p>23 well-designed case-control study, right?</p> <p>24 And a poorly-designed cohort</p> <p>25 study may be less valuable than a</p>
Page 295	Page 297
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Okay. Did each of the</p> <p>3 plaintiffs' experts address the issue of</p> <p>4 recall bias? Was that issue discussed in</p> <p>5 each and every one of their reports?</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: Again, I'd have</p> <p>8 to go through them and --</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Well, I assume you did that</p> <p>11 before today.</p> <p>12 A. And I don't have them</p> <p>13 memorized.</p> <p>14 Q. Okay.</p> <p>15 A. So if you'd like to go through</p> <p>16 them, I'm happy to sit here and we can go</p> <p>17 through each of them.</p> <p>18 Q. You know that's impossible,</p> <p>19 don't you? In seven hours, you know that's</p> <p>20 impossible, which is exactly why you're</p> <p>21 saying that.</p> <p>22 MR. LOCKE: Objection.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Let me ask you this, Doctor:</p> <p>25 You are going -- you are asking -- you are --</p>	<p>1 well-designed case-control study, right?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: It depends.</p> <p>5 Potentially.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Of course it depends.</p> <p>8 So the question is: Having</p> <p>9 been dependent upon that, it's incumbent upon</p> <p>10 you as a scientist to look at each study for</p> <p>11 the purpose of design, to see whether one is</p> <p>12 well-designed and one isn't, right?</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: Can you ask that</p> <p>15 again?</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Yes.</p> <p>18 Since epidemiology -- we went</p> <p>19 through the different examples -- requires</p> <p>20 you to not strictly adhere to a hierarchy but</p> <p>21 look at the particular designs of the</p> <p>22 studies, did you do that with respect to each</p> <p>23 one of these studies?</p> <p>24 A. I did.</p> <p>25 Q. Okay. So with regard to the</p>

75 (Pages 294 to 297)

Christian Merlo, M.D., MPH

Page 298	Page 300
<p>1 cohort studies, okay, did you look at 2 individually whether there was a particular 3 concern with these studies on 4 misclassification bias? 5 A. There's always a concern for 6 misclassification. 7 Q. Understood. Theoretically 8 that's true with every one of these cohort 9 studies. 10 But you know each of these 11 studies only asked these women in decades, 12 most cases decades -- I think the Nurses' 13 Health Study was six and a half years -- but 14 one -- only once about talc usage at the 15 beginning -- at or near the beginning of the 16 study, right? 17 MR. LOCKE: Objection. 18 THE WITNESS: We'd have to 19 break -- that's a very generalized 20 question. 21 QUESTIONS BY MR. TISI: 22 Q. Where is it in your report? 23 Where is it in your report? 24 A. I'm sorry. 25 MS. MILLER: Objection.</p>	<p>1 A. The analysis was done during 2 the follow-up period. 3 Q. Which was when? 4 How many decades after they 5 were initially asked? 6 A. Well, it depends on when the 7 patient -- when the study subject was 8 enrolled. 9 I can say that the Gertig 10 study, it was assessed -- the exposure 11 questionnaire was added in 1982, and they 12 were followed for 14 years on average. 13 Q. Right. 14 And in 14 years, isn't it 15 conceivable that somebody could have started 16 using talc, or somebody that who said they 17 were using talc stopped using talc? 18 A. That's certainly possible, but 19 for four studies to show the same 20 nondifferential misclassification, that would 21 be very, very unlikely. 22 Q. Right. 23 And four studies which asked -- 24 asked the question once at the beginning of 25 the study, right?</p>
Page 299	Page 301
<p>1 QUESTIONS BY MR. TISI: 2 Q. Where is your discussion in the 3 report about when they were asked about their 4 talc usage in the cohort studies? 5 A. Well, we can go through my 6 report if you'd like to. 7 Q. You just did that, Doctor, and 8 you said it wasn't here. 9 On page 24 and 25, you have a 10 discussion, the Gertig, Gates, Houghton and 11 Gonzalez studies. There is no discussion in 12 here about when they were asked about the 13 talc and how often they were asked. 14 MR. LOCKE: Objection. 15 THE WITNESS: I would have to 16 look back through my report because I 17 do know that in the Gertig study and 18 the Gates study, the questionnaire 19 that asked women about talc exposure 20 was in 1982. 21 QUESTIONS BY MR. TISI: 22 Q. Correct. 23 A. And so that is when they were 24 asked. 25 Q. And when was the analysis done?</p>	<p>1 MS. MILLER: Objection. 2 QUESTIONS BY MR. TISI: 3 Q. They all had the same flaw. 4 You had four flawed studies, didn't you? 5 MS. MILLER: Can we stick with 6 one question at a time? 7 QUESTIONS BY MR. TISI: 8 Q. You had four flawed studies 9 with respect to misclassification bias. They 10 all asked one time at the beginning of the 11 study; true or not true? 12 MR. LOCKE: Objection. 13 MS. MILLER: Objection. 14 THE WITNESS: The Gates and 15 Gertig study did ask women questions 16 about talc in 1982. That was the only 17 time that they were asked about talc 18 usage in those two studies. 19 QUESTIONS BY MR. TISI: 20 Q. What about Houghton? 21 A. In Gertig -- sorry, in -- let 22 me just do Gonzalez first. 23 Gonzalez were asked if they 24 used talc within 12 months prior to 25 enrollment into the study, and so that's</p>

76 (Pages 298 to 301)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 302</p> <p>1 going to depend on when they enrolled in the 2 study in between 2003 to 2009. And they were 3 followed for six years afterwards. 4 Q. And they were never -- just 5 while we're talking about that, were they 6 ever asked after enrollment, again, whether 7 or not they switched to using talc, or people 8 who said they were using talc stopped? 9 MS. MILLER: Objection. 10 THE WITNESS: They were not 11 asked again. 12 QUESTIONS BY MR. TISI: 13 Q. Okay. Houghton? 14 A. In Houghton, participants 15 were -- completed an annual questionnaire at 16 enrollment. And I don't know if I have the 17 specific year that the questionnaire was 18 asked, because study subject enrolled from 19 1993 to 1998 and then were followed -- 20 Q. How many years? 21 A. An average of 12 years. 22 Q. Okay. Were they ever asked in 23 that 12 years whether some who had been on 24 talc went off, or some who were off talc went 25 on in those 12 years?</p>	<p style="text-align: right;">Page 304</p> <p>1 study, do you? 2 MS. MILLER: Objection. Asked 3 and answered like ten times. 4 THE WITNESS: I addressed it in 5 the context of my report, and inherent 6 in any observational study is the 7 potential for misclassification. 8 QUESTIONS BY MR. TISI: 9 Q. You didn't analyze in your 10 report whether the cohort studies in talc 11 were flawed or limited in reliability by 12 misclassification studies, did you? 13 MS. MILLER: Objection. 14 THE WITNESS: Can you ask that 15 again? 16 QUESTIONS BY MR. TISI: 17 Q. Yes. 18 Other than making the general 19 observation, did you analyze in your report 20 whether the cohort talc studies were flawed 21 or limited in reliability by 22 misclassification bias? 23 A. So other than saying what I 24 said before, that inherent in all 25 observational studies, which I talked about</p>
<p style="text-align: right;">Page 303</p> <p>1 A. They weren't. 2 Q. Okay. So those were 3 limitations on the cohort studies, correct? 4 A. They're potential limitations 5 of a cohort study. 6 Q. And you don't address those in 7 your report, do you? 8 A. Again, it's inherent in a 9 cohort study that there are potential -- 10 there's potential exposure misclassification. 11 Q. I understand. 12 Did you address those -- well, 13 in cohort studies they can be asked every 14 year about their exposures, right? Some do 15 that. 16 A. And there's still potential for 17 misclassification. 18 Q. Understood. 19 But these particular studies 20 were particularly vulnerable to that bias 21 because they asked only once at the beginning 22 of the studies, true? 23 A. Not necessarily, no. 24 Q. Okay. But you don't address it 25 at all in the context of each individual</p>	<p style="text-align: right;">Page 305</p> <p>1 in my report, misclassification, other than 2 that -- that's what I talked about in my 3 report. 4 Q. Other than that, the answer is 5 no, you didn't discuss them in the context of 6 the individual studies? 7 MS. MILLER: Objection. 8 MR. LOCKE: Objection. 9 THE WITNESS: But I discussed 10 it within my report, which is within 11 the context of the individual studies. 12 QUESTIONS BY MR. TISI: 13 Q. Let's talk about strength of 14 the association. We talked about methodology 15 generally. Let's talk about strength. 16 On page 32 of your report, you 17 say -- you have a section called "Lack of 18 Strength of Associations." 19 Page 32, bottom, Section D. 20 A. Lack of Strength of 21 Association. 22 Q. Do you see that? 23 A. Yes. 24 Q. On page 33, you say, "The 25 heart -- the higher the relative risk, the</p>

77 (Pages 302 to 305)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 306</p> <p>1 greater the likelihood that the relationship 2 is causal." 3 A. I see that. 4 Q. You use the term "weak" or 5 "relatively weak" association seen in the 6 talc and ovarian cancer relationship, 7 correct? You call them weak. 8 A. Where are you? 9 Q. For example, the very -- the 10 very last -- the second full paragraph, last 11 three lines up you say, "Relatively weak 12 associations." 13 A. I'm not seeing where you're 14 referring to. 15 Q. Right there. 16 MS. MILLER: It's hard to see 17 upside down. 18 MR. TISI: Well, I can't do it 19 any other way unless you want me to 20 reach over and point at the witness. 21 I said three sentences up from 22 the second paragraph. 23 MS. MILLER: Three second up -- 24 from the bottom of the second 25 paragraph?</p>	<p style="text-align: right;">Page 308</p> <p>1 A. I wrote that in my report. 2 Q. Okay. And you cite a 1982 3 article by Widner. 4 A. That's correct. 5 Q. And on page 46, you state that 6 "Risk ratios between 1.2 and 1.6 are by 7 definition weak associations." 8 That's your conclusion 9 sentence. First sentence, third paragraph 10 down. 11 "This is by definition a weak 12 association." 13 A. That's correct. 14 Q. Okay. Where is that definition 15 written? 16 MS. MILLER: Objection. 17 THE WITNESS: Well, I would 18 have to go back and look at the 19 article that I referenced. 20 QUESTIONS BY MR. TISI: 21 Q. Is that the only -- is that the 22 only article that you can think of? 23 A. It's the only article that 24 comes to mind that I could find, but it's a 25 generally accepted -- generally accepted in</p>
<p style="text-align: right;">Page 307</p> <p>1 MR. TISI: Yeah. 2 MS. MILLER: Oh, okay. I see 3 it now. I misunderstood you. 4 THE WITNESS: I see that. 5 QUESTIONS BY MR. TISI: 6 Q. And on page 42, you say, "It is 7 generally accepted that risk ratios -- that 8 ratios of risk measures between 1.1 and 2.0 9 represent a weak association between exposure 10 and outcome." 11 A. What page is that on? 12 Q. 42. 13 A. And where is that? 14 Q. I'm sorry. I'm sorry, page 43, 15 second paragraph. "Although there is no 16 universe numeric definition of a strong 17 association between exposure and risk, it is 18 generally accepted that risk -- that ratios 19 of risk measures between 1.1 and 2.0 20 represent a weak association between exposure 21 and outcome." 22 Is that right? 23 Did you say that? 24 A. Did I -- 25 Q. Yes.</p>	<p style="text-align: right;">Page 309</p> <p>1 the epidemiologic community that anything 2 less than 2 is a weak association. 3 Q. Anything less than 2 is weak? 4 A. So, again, it depends, because 5 there are certain studies that may show, that 6 have been designed properly, that bias and 7 confounding aren't a problem, that analysis 8 is great and interpretation is fine where 9 that association, that relative risk, even 10 though it's less than 2 considered weak, that 11 may be -- that may point towards causality 12 between an exposure and an outcome. 13 However, when bias and 14 confounding are potential to be present -- 15 for instance, if we're going to talk about 16 confounding, which I think I should -- 17 Q. I'm asking you about the 18 definition, where, by definition, something 19 less than 2.0 is weak. 20 A. It's a generally accepted -- 21 Q. Generally accepted? 22 A. It's generally accepted in the 23 epidemiology community. 24 (Merlo Exhibit 31 marked for 25 identification.)</p>

78 (Pages 306 to 309)

Christian Merlo, M.D., MPH

Page 310	Page 312
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. I'm going to show you</p> <p>3 Exhibit Number 31, which is the National</p> <p>4 Cancer Institute statements on ovarian</p> <p>5 cancer.</p> <p>6 Have you seen this before?</p> <p>7 A. No.</p> <p>8 MR. LOCKE: Objection.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Okay. If you look at the</p> <p>11 second page, it talks about factors within --</p> <p>12 "with adequate evidence of increased risk of</p> <p>13 ovarian, fallopian tube and primary</p> <p>14 peritoneal cancers."</p> <p>15 Do you see that?</p> <p>16 A. I see that.</p> <p>17 Q. You see they talk about</p> <p>18 endometriosis.</p> <p>19 MS. MILLER: Can you point me</p> <p>20 to that?</p> <p>21 MR. TISI: Yeah. You see where</p> <p>22 endometriosis is?</p> <p>23 MS. MILLER: No, that's why I'm</p> <p>24 asking you to point --</p> <p>25 MR. TISI: It's on page 3 of</p>	<p>1 magnitude of effect modest with observed</p> <p>2 relative risks of 1.2 to 1.8.</p> <p>3 Q. Do you think the National</p> <p>4 Cancer Institute doesn't understand the --</p> <p>5 doesn't understand the concept of strength of</p> <p>6 association and this generally accepted</p> <p>7 principle that anything under 2.0 is weak?</p> <p>8 MS. MILLER: Objection.</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: So again, I'm not</p> <p>11 here to give an opinion on the</p> <p>12 National Cancer Institute. I don't</p> <p>13 know who put this document together,</p> <p>14 and I did say that it depends. It</p> <p>15 depends on the study.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay.</p> <p>18 A. But in general, a relative risk</p> <p>19 of -- or an odds ratio of less than 2 is a</p> <p>20 weak association.</p> <p>21 Q. What about obesity and height,</p> <p>22 the next one? It says, based on fair</p> <p>23 evidence -- not even great evidence but fair</p> <p>24 evidence -- obesity and height are associated</p> <p>25 with a modest increased risk of ovarian</p>
Page 311	Page 313
<p>1 18.</p> <p>2 MS. MILLER: Oh, sorry, I was</p> <p>3 on page 4. I thought you said</p> <p>4 factors.</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. See endometriosis?</p> <p>7 Do you see that?</p> <p>8 A. I do see that.</p> <p>9 Q. See it talks about this is an</p> <p>10 established risk of ovarian cancer? The</p> <p>11 magnitude of the effect is described as</p> <p>12 modest with 1.8 to 2.4.</p> <p>13 MS. MILLER: Objection.</p> <p>14 Mischaracterizes the document.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Do you see that?</p> <p>17 A. I see a statement that says,</p> <p>18 magnitude of effect --</p> <p>19 Q. Okay.</p> <p>20 A. -- modest with observed</p> <p>21 relative risks of 1.8 to 2.4.</p> <p>22 Q. Do you see magnitude of effect</p> <p>23 for hormone replacement therapy, modest with</p> <p>24 observed relative risk, 1.20 to 1.8?</p> <p>25 A. I do see the statement</p>	<p>1 cancer, and they defined it as a 1.1.</p> <p>2 Do you see that?</p> <p>3 A. I see, based on fair evidence,</p> <p>4 increases in height and body mass indexes are</p> <p>5 associated with a modest increase in risk of</p> <p>6 ovarian cancer.</p> <p>7 And then where are you seeing</p> <p>8 the 1.1?</p> <p>9 Q. The next paragraph.</p> <p>10 A. I do see that.</p> <p>11 Q. So the National Cancer</p> <p>12 Institute, at least with respect to ovarian</p> <p>13 cancer, has classified modest increases from</p> <p>14 anywhere between 1.1 all the way up to 2.0 as</p> <p>15 modest, correct?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Again, I'm not</p> <p>19 sure who put this all together, but if</p> <p>20 I were to give a presentation and</p> <p>21 say -- in a classroom or in a lecture</p> <p>22 or in my research progress and said</p> <p>23 that a risk ratio of 1.1 was modest,</p> <p>24 I'd get laughed out of the room.</p> <p>25 QUESTIONS BY MR. TISI:</p>

Christian Merlo, M.D., MPH

Page 314	Page 316
<p>1 Q. So this is a laughable 2 document, huh? 3 MR. LOCKE: Objection. 4 THE WITNESS: I'm not saying 5 I'm laughing at this, but I'm just 6 telling you that if Dr. Gordis came 7 into the room and I tried to explain 8 to him that a relative risk of 1.1 is 9 modest, he'd laugh me out of the room. 10 QUESTIONS BY MR. TISI: 11 Q. Now he's an expert? 12 A. I'm not saying he's an expert. 13 Q. Okay. 14 A. He was my teacher. 15 Q. Okay. 16 A. And I wouldn't do that in front 17 of him. 18 (Merlo Exhibit 32 marked for 19 identification.) 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Let's look at Exhibit 22 Number 32, which is another chapter out of 23 the textbook Modern Epidemiology by 24 Dr. Rothman, which I have marked as Exhibit 25 Number 32. And on page 25 of 30, it talks</p>	<p>1 But because of other factors, 2 maybe factors, considerations that Bradford 3 Hill has, such as consistency or dose 4 response, do lead one to conclude that 5 there's a causal association between exposure 6 and outcome. 7 And if we're talking about 8 environmental tobacco smoke and lung cancer, 9 studies are consistent, and there's a 10 consistent dose response. 11 Q. They all show -- they all 12 show -- they all show statistically 13 significant associations. Every cohort and 14 case-control study shows consistent 15 association in secondhand smoke; is that what 16 you're testifying to? 17 MS. MILLER: Objection. 18 MR. LOCKE: Objection. 19 THE WITNESS: I didn't say 20 that. 21 QUESTIONS BY MR. TISI: 22 Q. Okay. 23 A. I said that there's 24 consistency. And there's consistency in the 25 literature that secondhand smoke in</p>
Page 315	Page 317
<p>1 about the strength criteria. 2 He says -- and I want to ask 3 you whether you agree with it or not -- under 4 the strength of association, second -- two 5 sentences from the bottom of the first 6 paragraph, "Of special importance, Cornfield, 7 et al., acknowledged that having only a weak 8 association does not rule out causal 9 association. Today, some associations, such 10 as those between smoking and cardiovascular 11 disease or between environmental tobacco 12 smoke and lung cancer are accepted by most as 13 causal, even though the associations are 14 considered weak." 15 Do you agree with that? 16 A. So I'm going to -- if you just 17 give me a second to read it over again. 18 Q. Uh-huh. 19 A. Because I'm seeing this for the 20 first time. 21 So again, we're talking about 22 generalizations here, and there are -- there 23 may be instances where a relative risk or an 24 odds ratio is less than 2, and it's 25 considered a weak association.</p>	<p>1 sufficient dose over sufficient time -- so a 2 dose response plus consistency -- can lead 3 one to conclude that there is a causal 4 association between secondhand smoke and, 5 say, lung cancer. 6 Q. So where is the statement that 7 you have to -- in the absence of a high risk 8 ratio or in the presence of a weak risk ratio 9 that you need to have dose response and 10 consistency? 11 A. Because -- 12 Q. Or is that -- is that your 13 postulate? 14 A. No, that is not my postulate. 15 That's -- those things oftentimes go 16 hand in hand. And the reason I say this, if 17 there's a relative risk of 200, it's going to 18 be very difficult to explain that away. 19 Say we used the pulmonary 20 hypertension example. The odds ratio is 23 21 for patients that use that medication for 22 more than three months. So -- and that gets 23 at the dose response and gets at the factors 24 that may -- the other considerations that 25 Bradford Hill brought out, namely, namely,</p>

80 (Pages 314 to 317)

Christian Merlo, M.D., MPH

Page 318	Page 320
<p>1 the dose response.</p> <p>2 So secondhand smoke over a</p> <p>3 sufficient amount of time, given a sufficient</p> <p>4 amount of exposure, even though there may be</p> <p>5 a weak relative risk, that potentially could</p> <p>6 be a causal -- could -- one could conclude</p> <p>7 causality because of the other considerations</p> <p>8 that are present.</p> <p>9 Q. On the next page -- I'm going</p> <p>10 to ask you about secondhand smoke. Before I</p> <p>11 do, let's go to the next page. It says,</p> <p>12 "These examples remind us that a strong</p> <p>13 association is neither necessary nor</p> <p>14 sufficient for causality and that weakness</p> <p>15 isn't even necessary nor sufficient for the</p> <p>16 absence of causality."</p> <p>17 Do you see that?</p> <p>18 A. Is that the second sentence on</p> <p>19 the top?</p> <p>20 Q. Yes. "These examples remind us</p> <p>21 that a strong association is neither</p> <p>22 necessary nor sufficient for causality and</p> <p>23 that weakness is neither necessary nor</p> <p>24 sufficient for absence of causality."</p> <p>25 Do you agree with that?</p>	<p>1 objection that this is an excerpt that</p> <p>2 was cut off at the end, and it's not a</p> <p>3 complete chapter or a complete</p> <p>4 anything.</p> <p>5 MR. TISI: Okay. Well, it's a</p> <p>6 complete paragraph that talks about</p> <p>7 the strength of association, so</p> <p>8 let's...</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: I'm sorry, I just</p> <p>11 need a little bit of time to find it.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. That's fine.</p> <p>14 A. Okay. So I have three pages</p> <p>15 photocopied here.</p> <p>16 Q. Correct.</p> <p>17 So if you go to the last page,</p> <p>18 it has a paragraph with a bullet point that</p> <p>19 says, "Strength of Association."</p> <p>20 Do you see that?</p> <p>21 And if you read it and tell me</p> <p>22 where Dr. Oleckno talks about strong,</p> <p>23 moderate and weak associations.</p> <p>24 MS. MILLER: Objection.</p> <p>25 MR. LOCKE: Objection.</p>
Page 319	Page 321
<p>1 A. So I think that this is one of</p> <p>2 the -- one of the things that Bradford Hill</p> <p>3 in his article said, that these are</p> <p>4 considerations, and that if there is a risk</p> <p>5 ratio, whether it's a relative risk or a odds</p> <p>6 ratio of 200, it's difficult to explain that</p> <p>7 away.</p> <p>8 Could it be explained away?</p> <p>9 Sure, if we didn't measure some factor that</p> <p>10 is associated with the exposure and the</p> <p>11 outcome and is not in between the causal</p> <p>12 pathway. But it -- it's a reason to use</p> <p>13 these as considerations.</p> <p>14 And further, if we're talking</p> <p>15 about a weak association, say a weak relative</p> <p>16 risk or odds ratio, that less than 2, if</p> <p>17 there are other considerations that add to</p> <p>18 it, say dose response or consistency among</p> <p>19 studies, then that supports causality.</p> <p>20 Q. Let me go to the Oleckno</p> <p>21 article -- the Oleckno textbook again, and</p> <p>22 let me ask you this. He also -- it's the</p> <p>23 same one we talked about before. So we can</p> <p>24 go to Exhibit Number 22.</p> <p>25 MS. MILLER: I have the same</p>	<p>1 THE WITNESS: I think the</p> <p>2 Oleckno textbook says in general, the</p> <p>3 stronger an association between a</p> <p>4 given exposure and outcome, the more</p> <p>5 likely association is causal.</p> <p>6 It's also referencing a table,</p> <p>7 6.3, which is not here, so I'm not</p> <p>8 sure how I can even answer that.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Yeah, but you said -- but,</p> <p>11 Doctor, you said here -- you said here at the</p> <p>12 end "by definition." You use the phrase "by</p> <p>13 definition," "a 1.2 to 1.6 by definition is</p> <p>14 weak."</p> <p>15 And I don't see that</p> <p>16 definition, so you need to tell me where that</p> <p>17 definition is.</p> <p>18 A. It's an accepted definition in</p> <p>19 epidemiology.</p> <p>20 MS. MILLER: Objection.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. By whom?</p> <p>23 A. Epidemiologists.</p> <p>24 Q. Where?</p> <p>25 I've gone through every</p>

81 (Pages 318 to 321)

Christian Merlo, M.D., MPH

Page 322	Page 324
<p>1 textbook and I've never seen a definition, 2 and you don't provide it. So I want to know 3 where you find it -- 4 MR. LOCKE: Objection. 5 MS. MILLER: Objection. 6 QUESTIONS BY MR. TISI: 7 Q. -- other than the Australian 8 thing that we talked about before. Where? 9 MS. MILLER: Objection. 10 MR. LOCKE: Objection. 11 THE WITNESS: It's in my 12 reference. We can pull that and look 13 at it, if you'd like. 14 QUESTIONS BY MR. TISI: 15 Q. Okay. I'm going to find it in 16 your references? 17 A. It's that reference. 18 Q. Okay. That Australian white 19 paper? 20 MS. MILLER: Objection. 21 THE WITNESS: Let me look 22 through. I'll look through my report 23 again. 24 QUESTIONS BY MR. TISI: 25 Q. Actually, Doctor, I think</p>	<p>1 MR. LOCKE: Objection. 2 MS. MILLER: Objection. 3 QUESTIONS BY MR. TISI: 4 Q. You're cherry-picking. 5 I'm going to show you what 6 Dr. Siemiatycki says. Actually, let me just 7 choose actually -- I'm going to choose 8 Dr. Siemiatycki. Here's his report. I'm 9 going to attach it as Exhibit Number 33, his 10 discussion of that issue. 11 (Merlo Exhibit 33 marked for 12 identification.) 13 QUESTIONS BY MR. TISI: 14 Q. He's one of the people you 15 criticize, right? 16 A. I critiqued plaintiffs' 17 reports. 18 Q. Right. 19 And you say, "Dr. Siemiatycki 20 states," and you have a quote, which indeed I 21 will tell you appears in the report, but it's 22 not the whole thing of what he says. Does 23 it -- would you agree? 24 MS. MILLER: Objection. 25 THE WITNESS: Can you ask that</p>
Page 323	Page 325
<p>1 that's where it is. I'm not going to ask you 2 to move on. 3 But you criticize plaintiffs' 4 experts because they say -- they call this 5 strong, this 1.2 to 1.6 as strong. 6 Do you see that? Page 43 of 7 your report? 8 A. I do see that. Plaintiffs' 9 epidemiologists find a strong association. 10 Q. Did you actually read their 11 reports? 12 A. I did. 13 MR. LOCKE: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. Did you read their depositions? 16 A. I did. 17 Q. Did you read -- did you read 18 where they explained what they were talking 19 about in terms of strength of association? 20 MS. MILLER: Objection. 21 THE WITNESS: So you would have 22 to -- 23 QUESTIONS BY MR. TISI: 24 Q. I mean, you're cherry-picking 25 what they said, aren't you?</p>	<p>1 again? I'm not sure what you're 2 asking me. 3 QUESTIONS BY MR. TISI: 4 Q. Yes. I'm going to read his 5 section that talks about strength of 6 association. 7 MS. MILLER: I'm going to 8 object to this -- 9 MR. TISI: Of course you're 10 going to object because it's -- 11 MS. MILLER: -- specific 12 because it's page 19 and then it's 13 page 62, 63, 87, 88, 82. 14 MR. TISI: Yes. These are the 15 two -- this is every place in his 16 report where he talks about strength 17 of association. Absolutely. 18 MS. MILLER: Well, I don't have 19 a need to know that. 20 MR. TISI: Including -- 21 actually, it has -- it has the -- it 22 has the very quote that this doctor 23 put in his report, and I'll put it 24 there. It's page 63. "Such a high 25 and significant meta-analysis research</p>

82 (Pages 322 to 325)

Christian Merlo, M.D., MPH

Page 326	Page 328
<p>1 risk ratio could not have occurred by 2 chance." 3 QUESTIONS BY MR. TISI: 4 Q. Do you see that? 5 MR. LOCKE: Objection. 6 QUESTIONS BY MR. TISI: 7 Q. It's on page 63, and that's the 8 quote you had. 9 MS. MILLER: You objected to 10 cherry-picking. These are seven 11 cherry-picked pages from an expert 12 report. 13 MR. TISI: They're not 14 cherry-picked pages. Every part that 15 talks about -- 16 MS. MILLER: I don't know what 17 cherry-picked means to you, but -- 18 MR. TISI: Well, Counsel, then 19 keep your objections to yourself. 20 MR. LOCKE: Objection. 21 MR. TISI: "Objection, form," 22 is fine. 23 QUESTIONS BY MR. TISI: 24 Q. Doctor, this is the paragraph 25 that you quote in your report, correct? It's</p>	<p>1 That means the best estimate from an ep -- 2 from the epidemiologic literature is that 3 women who regularly used talcum powder 4 products in the genital area had a 28 percent 5 higher risk of ovarian cancer than a woman 6 who did not use such powder. As I illustrate 7 in Table 11, which I attach" -- because it 8 refers to there, if you take a look on 9 page -- at the -- on page 87, it has a 10 Table 11. He lists numerous kinds of -- 11 urban air pollution, trichloroethylene, 12 diesel engine emissions, benzene, domestic 13 radon gas, secondhand cigarette smoke, 14 intermittent, intense sun exposure, et 15 cetera. He lists a lot of them, all within a 16 relative risk of 1.09, with the highest being 17 1.64. 18 Do you see that table? 19 A. I do. 20 Q. "As I illustrate in Table 11 21 with a few examples, this relative risk is in 22 line with well-recognized risk factors for 23 cancer and other diseases. For example, it 24 is well-accepted now that people living in an 25 urban neighborhood in which there is -- in</p>
Page 327	Page 329
<p>1 the last sentence of a full paragraph. 2 A. I'd have to look at his full 3 report to know if that's the one I'm quoting. 4 Said that again somewhere. 5 Q. Okay. Doctor, it says, "Such a 6 high" -- you look at your report on page 43. 7 It says, "Such a high and significant," in 8 parentheses, "relative risk could not have 9 occurred by chance." And that's the sentence 10 on page 63. 11 A. So we're looking at page 63 12 of -- 13 Q. Correct. 14 A. -- Dr. Siemiatycki's report. 15 Q. Right. 16 And that's at the end of a 17 paragraph, right? 18 A. That's at the end of a 19 paragraph. 20 Q. Okay. So let's look at what he 21 says before that. 22 "Strength of association. This 23 can embody both the magnitude of the relative 24 risk and its statistical significance. The 25 meta-analysis risk ratio estimate is 1.28.</p>	<p>1 which the air is highly polluted with 2 particulate matter have a 5 to 10 percent 3 excess risk of lung cancer compared to people 4 living in a less polluted urban neighborhood. 5 Also is well-accepted that workers exposed to 6 a solvent called trichloroethylene had about 7 a 40 percent higher chance of kidney cancer 8 compared to workers not exposed to 9 trichloroethylene. Thus, the 28 percent 10 increase in ovarian cancer for women who used 11 talcum powder products is in line with many 12 risk factors. This increased risk is 13 manifested by a meta research -- meta risk 14 ratio that is statistically significant." 15 And then it has the sentence you quoted. 16 He's very clear about the range 17 of relative risks and compares it to a number 18 of other well-accepted carcinogens, does he 19 not? 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 THE WITNESS: I see that there 23 is a comparison to other agents and 24 potential risk for disease in those 25 agents.</p>

83 (Pages 326 to 329)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 330</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. And you --</p> <p>3 A. However, this says nothing</p> <p>4 about the strength of association. It just</p> <p>5 says that there's an association between</p> <p>6 these agents and this disease with this</p> <p>7 relative risk.</p> <p>8 These are all under 2. That</p> <p>9 doesn't -- that says nothing about the</p> <p>10 strength. It's a weak association of all of</p> <p>11 them.</p> <p>12 Q. Okay. Then he goes on and he's</p> <p>13 asked about that in his deposition, and I'm</p> <p>14 going to attach that. And I'm not going to</p> <p>15 spend a lot of time on it, but for the</p> <p>16 record, that will be on the record, Exhibit</p> <p>17 Number 34.</p> <p>18 (Merlo Exhibit 34 marked for</p> <p>19 identification.)</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. And did you cite anything from</p> <p>22 his deposition?</p> <p>23 MS. MILLER: Objection.</p> <p>24 THE WITNESS: I'd have to look</p> <p>25 through my report.</p>	<p style="text-align: right;">Page 332</p> <p>1 MS. MILLER: Again, I'm going</p> <p>2 to have to have the same objection. I</p> <p>3 don't know why you didn't just provide</p> <p>4 the entire expert report.</p> <p>5 This is pages 11, 12, 13, 14,</p> <p>6 15, 16. We don't have pages 1 to 10.</p> <p>7 We don't have --</p> <p>8 MR. TISI: Counsel, I got your</p> <p>9 objection. I got your --</p> <p>10 MS. MILLER: -- pages after 16,</p> <p>11 and page 16 ends in the middle of a</p> <p>12 sentence.</p> <p>13 MR. TISI: I got your -- I got</p> <p>14 your objection, Counsel.</p> <p>15 MR. LOCKE: Same objection.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Doctor, can you turn to page 15</p> <p>18 of Dr. Moorman's report, which I have put</p> <p>19 here, which I will represent to you is a</p> <p>20 whole section on strength of association.</p> <p>21 She has a paragraph, "The</p> <p>22 overall association seen in talc/ovarian</p> <p>23 cancer meta-analyses, as well as many other</p> <p>24 individual studies, are statistically</p> <p>25 significant, indicating an increased risk of</p>
<p style="text-align: right;">Page 331</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Let me show you another</p> <p>3 example: Dr. Moorman. Dr. Moorman, who you</p> <p>4 also criticize as saying, "Taken as a whole,</p> <p>5 the overwhelming statistical strength of</p> <p>6 these studies" -- sorry, "by the strength of</p> <p>7 the studies, whose results are replicated</p> <p>8 over decades and over a wide variety of</p> <p>9 populations and investigators, further</p> <p>10 supported by consistent meta-analysis, weigh</p> <p>11 heavily in favor of a causal inference."</p> <p>12 That was what you said that</p> <p>13 Dr. Moorman said, correct?</p> <p>14 A. You'd have to refer to me where</p> <p>15 I said that.</p> <p>16 Q. On page 43 and 44 of your</p> <p>17 report.</p> <p>18 A. And I apologize. I don't have</p> <p>19 these -- this memorized. So, you know,</p> <p>20 you're reading stuff --</p> <p>21 Q. Well, I do, and I didn't write</p> <p>22 it. Here you go.</p> <p>23 MS. MILLER: Objection.</p> <p>24 (Merlo Exhibit 35 marked for</p> <p>25 identification.)</p>	<p style="text-align: right;">Page 333</p> <p>1 approximately 25 to 30 percent. While not as</p> <p>2 high as other relationship, like smoking and</p> <p>3 lung cancer, these relative risks are in line</p> <p>4 with other generally accepted causal</p> <p>5 relationships. Example, secondhand smoke and</p> <p>6 lung cancer: I consider the strength of</p> <p>7 association as seen in the ovarian cancer</p> <p>8 epidemiologic studies to be an important</p> <p>9 factor in favor of a causal relationship</p> <p>10 between talc and ovarian cancer, particularly</p> <p>11 when considered along with the consistency</p> <p>12 and association seen across these studies."</p> <p>13 Dr. Moorman is not -- has</p> <p>14 characterized what the studies show. The</p> <p>15 numbers are the numbers, correct?</p> <p>16 MS. MILLER: Objection.</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: You'd have to</p> <p>19 show me what you're referring to. The</p> <p>20 numbers are the numbers.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. All right. Well, let's do</p> <p>23 that. Dr. Moorman --</p> <p>24 MS. MILLER: This is only part</p> <p>25 of her report, and it's not the part</p>

84 (Pages 330 to 333)

Christian Merlo, M.D., MPH

Page 334	Page 336
<p>1 of her report that he cites. Is that 2 correct? 3 (Merlo Exhibit 36 marked for 4 identification.) 5 QUESTIONS BY MR. TISI: 6 Q. Here's your -- here's Exhibit 7 Number 36, please. 8 She's asked the questions on 9 page 249 of her report -- of her deposition. 10 "I think you're conflating or 11 misunderstanding my question." This is the 12 Johnson & Johnson lawyer asking the question. 13 "I think you're conflating or 14 you're misunderstanding my question because 15 you're answering the question" -- 16 A. I'm sorry, where are we? 17 Q. Page 249, starting on line 3. 18 Okay? "And I think you're 19 conflating or you're misunderstanding my 20 question because you're answering the 21 question about whether the association is 22 real or not real, and my question for you is 23 whether the association is weak, modest or 24 strong. How would you characterize it?" to 25 Dr. Moorman.</p>	<p>1 saying that I think it's more accurate 2 just to describe it as it is, a 25 to 3 30 percent increase of risk of ovarian 4 cancer, but I don't know what she's 5 referring to there -- 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. -- whether that's one study, 9 all studies, a meta-analysis, anything. 10 Q. Okay. 11 A. One could also say that a 12 relative risk of 1.25 or 1.30 is a weak 13 association. 14 Q. Okay. But you are 15 characterizing what they testified to, and 16 you were cherry-picking statements from their 17 report, were you not? 18 MS. MILLER: Objection. 19 MR. LOCKE: Objection. 20 THE WITNESS: I don't know what 21 you mean by "cherry-picking." 22 QUESTIONS BY MR. TISI: 23 Q. Meaning taking -- 24 A. I read their depositions -- 25 sorry, I read their reports and I critiqued</p>
Page 335	Page 337
<p>1 Her answer: "Answer, as I 2 would -- as I have said, there is no absolute 3 terminology that would say what is a weak 4 association, what is modest and what is 5 strong. So I think it is more accurate just 6 to describe it as it is, a 25 to 30 percent 7 increased risk of ovarian cancer." 8 Do you see that? 9 A. I see that. 10 Q. Okay. She didn't characterize 11 it as strong, did she? 12 MS. MILLER: Objection. 13 MR. LOCKE: Objection. 14 QUESTIONS BY MR. TISI: 15 Q. She characterized it by the 16 number, correct? 17 MS. MILLER: Objection. 18 MR. LOCKE: Objection. 19 MS. MILLER: Are you asking 20 ever or here or -- 21 MR. TISI: I'm asking -- I'm 22 asking when she was asked the question 23 at deposition. 24 MR. LOCKE: Objection. 25 THE WITNESS: Dr. Moorman is</p>	<p>1 their reports. And by saying that a relative 2 risk of 1.2 is a strong association is so far 3 out of line of the epidemiologic community 4 that that is my critique. 5 MR. TISI: Okay. We're about 6 ready to go into a new area, so if you 7 want to take a break, this is a good 8 time unless you want me to just plow 9 forward. 10 MS. MILLER: How long is the 11 next area? 12 MR. TISI: I have no idea. It 13 depends on whether he says "it 14 depends" all the time. 15 MR. LOCKE: Objection. 16 THE WITNESS: I can take a 17 break. 18 MR. TISI: Perfect. 19 THE WITNESS: Get some coffee. 20 MR. TISI: Perfect. 21 VIDEOGRAPHER: The time is 22 3:01 p.m. We're going off the record. 23 (Off the record at 3:01 p.m.) 24 VIDEOGRAPHER: The time is 25 3:16 p.m., and we're back on the</p>

85 (Pages 334 to 337)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 338</p> <p>1 record.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Doctor, could you go to page 31</p> <p>4 of your report? I'm going to talk about</p> <p>5 consistency and statistical significance.</p> <p>6 A. Sure.</p> <p>7 Q. We've spent a lot of time</p> <p>8 talking about consistency and your opinion</p> <p>9 that there is no consistency, so I think</p> <p>10 we'll be able to go through this pretty</p> <p>11 quickly.</p> <p>12 But if you go to page 31, you</p> <p>13 criticize plaintiffs' experts -- well, you</p> <p>14 say, "Lack of consistency between studies.</p> <p>15 One of the most striking aspects of their</p> <p>16 studies is their inconsistency."</p> <p>17 Do you see that?</p> <p>18 A. No.</p> <p>19 Where am I saying that?</p> <p>20 Q. First sentence of your</p> <p>21 Section A on page 31.</p> <p>22 A. Okay.</p> <p>23 Q. Okay. And you note, and I'm</p> <p>24 summarizing here, that there are seven</p> <p>25 hospital-based studies, four cohort studies</p>	<p style="text-align: right;">Page 340</p> <p>1 are the risk ratios, correct?</p> <p>2 A. Yes, the first column's the</p> <p>3 study authors and the dates. The second</p> <p>4 column is either the odds ratio, relative</p> <p>5 risk or hazard ratio.</p> <p>6 Q. Can we call them risk ratios</p> <p>7 generally?</p> <p>8 Can we call them -- is there a</p> <p>9 general -- I thought we could call them risk</p> <p>10 ratios, but --</p> <p>11 A. Sure. It's just that in an --</p> <p>12 an odds ratio is something that's determined</p> <p>13 in a case-control study and a relative risk,</p> <p>14 which in a hazard ratio deal with time, and</p> <p>15 those are involved in cohort studies.</p> <p>16 Q. I understand. I understand.</p> <p>17 But the second column are the</p> <p>18 risk ratios generally?</p> <p>19 A. Estimates of risk, yes.</p> <p>20 Q. Estimates of risk.</p> <p>21 And the third column are the</p> <p>22 confidence interval.</p> <p>23 And tell me what a confidence</p> <p>24 interval is.</p> <p>25 A. A confidence interval is when</p>
<p style="text-align: right;">Page 339</p> <p>1 and some population studies that have</p> <p>2 statistically insignificant results.</p> <p>3 And we talked about that</p> <p>4 before; do you recall?</p> <p>5 A. We talked about cohort studies.</p> <p>6 We talked about hospital-based studies. We</p> <p>7 talked about population-based studies. We</p> <p>8 talked about statistical significance in</p> <p>9 population-based studies as well as</p> <p>10 statistical insignificance in</p> <p>11 population-based studies as well as</p> <p>12 statistical insignificance in hospital-based</p> <p>13 and statistical insignificance within cohort</p> <p>14 studies.</p> <p>15 Q. Right.</p> <p>16 And on page 34 of your report,</p> <p>17 you have a chart that you put in summarizing</p> <p>18 the studies, correct?</p> <p>19 A. Page 34 is a chart that</p> <p>20 summarizes case-control studies as well as</p> <p>21 cohort studies, and the case controls are</p> <p>22 broken down into hospital-based and</p> <p>23 population-based.</p> <p>24 Q. And the first column is</p> <p>25 actually the study name. The second column</p>	<p style="text-align: right;">Page 341</p> <p>1 you do an analysis and you get a -- some</p> <p>2 estimate of risk, some point estimate, which</p> <p>3 would be that second column. Then you're</p> <p>4 given -- then you obtain what's called a</p> <p>5 95 percent confidence interval, which is sort</p> <p>6 of the range within statistical significance</p> <p>7 where that point estimate might fall.</p> <p>8 Q. Right.</p> <p>9 A. And in general, when the</p> <p>10 95 percent confidence interval overlies 1,</p> <p>11 that signifies a nonstatistically significant</p> <p>12 point -- estimate of risk.</p> <p>13 Q. But the confidence interval</p> <p>14 encompasses the range of likely -- where the</p> <p>15 likely results are likely to be to a</p> <p>16 95 percent certainty?</p> <p>17 A. The -- I don't know that I</p> <p>18 would say certainty. I think it's the --</p> <p>19 it's the range of the -- it's the range of</p> <p>20 the point estimate above which or below which</p> <p>21 there would be a 2.5 percent chance of that</p> <p>22 point estimate falling.</p> <p>23 Q. Okay.</p> <p>24 A. And the confidence interval can</p> <p>25 either be wide or narrow. The wider it is,</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 342</p> <p>1 that usually relates to heterogeneity within</p> <p>2 the study, a small study population, problems</p> <p>3 in collecting appropriate information.</p> <p>4 If the confidence interval is</p> <p>5 narrow, usually that reflects a larger study</p> <p>6 population.</p> <p>7 Q. And the last column is your</p> <p>8 assessment of the strength of the</p> <p>9 association, if there is one, right?</p> <p>10 You say, "Is it a statistically</p> <p>11 significant association?"</p> <p>12 And that's your interpretations</p> <p>13 here, correct?</p> <p>14 A. It says, "If there's a</p> <p>15 statistically significant association."</p> <p>16 That's what's reported in the journal.</p> <p>17 Q. Okay. And then the "no" in the</p> <p>18 last column stands for not statistically</p> <p>19 significant?</p> <p>20 A. The "no" stands for not</p> <p>21 statistically significant, that's correct.</p> <p>22 Q. And the "weak" stands for</p> <p>23 statistically significant and with your</p> <p>24 characterization of the strength of the</p> <p>25 association?</p>	<p style="text-align: right;">Page 344</p> <p>1 separate exhibit.</p> <p>2 (Merlo Exhibit 37 marked for</p> <p>3 identification.)</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. And I'm going to do it Exhibit</p> <p>6 Number 37.</p> <p>7 A. Thank you.</p> <p>8 Q. I'm going to come back to it,</p> <p>9 and I don't want to keep flipping back and</p> <p>10 forth to the pages.</p> <p>11 A. Okay.</p> <p>12 Q. And this is your -- this chart</p> <p>13 summarizes the -- the last column here</p> <p>14 summarizes your view of the inconsistency of</p> <p>15 these studies. The now are inconsistency</p> <p>16 with the weak's?</p> <p>17 MS. MILLER: Objection.</p> <p>18 THE WITNESS: So what -- not</p> <p>19 only that, I mean, what this does</p> <p>20 summarize, inconsistency within</p> <p>21 population-based case-control studies</p> <p>22 where some studies show a weak</p> <p>23 statistically significant association</p> <p>24 while some studies do not show any</p> <p>25 statistically significant association.</p>
<p style="text-align: right;">Page 343</p> <p>1 A. The "weak" stands for a weak</p> <p>2 statistically significant association.</p> <p>3 Q. But that's your</p> <p>4 characterization; that's not the authors'?</p> <p>5 A. That is what is -- they're all</p> <p>6 below 2, statistically significant --</p> <p>7 Q. Okay.</p> <p>8 A. Which -- suggests a weak</p> <p>9 association, yes.</p> <p>10 Q. Okay. And just to be clear,</p> <p>11 you can't point to me any textbook in</p> <p>12 epidemiology where it is universally accepted</p> <p>13 that a risk ratio of 1.17, which is one of</p> <p>14 the things -- to 1.92 is weak. That's just</p> <p>15 your view of what the scientific community</p> <p>16 says?</p> <p>17 MS. MILLER: Objection.</p> <p>18 MR. LOCKE: Objection.</p> <p>19 THE WITNESS: It's not my view</p> <p>20 of what the scientific community says.</p> <p>21 It's what the scientific community</p> <p>22 says.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. Okay. And you -- okay. I'd</p> <p>25 like to make this chart a separate chart -- a</p>	<p style="text-align: right;">Page 345</p> <p>1 But there's also differences</p> <p>2 in -- within study -- the same study</p> <p>3 design. Say, within case controls,</p> <p>4 hospital-based case controls, there</p> <p>5 are seven of them, and none of them</p> <p>6 have a statistically significant</p> <p>7 association, and therefore case con --</p> <p>8 sorry, four cohort studies which do</p> <p>9 not show any statistically</p> <p>10 significant.</p> <p>11 So it's not just summarizing</p> <p>12 the differences in that column, it's</p> <p>13 summarizing the differences between</p> <p>14 study types and the differences within</p> <p>15 a similar study.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Understood. And I hear you.</p> <p>18 And what I'm trying to say is,</p> <p>19 it's your view that a weak statistically</p> <p>20 significant result is inconsistent with a</p> <p>21 non -- and I think you agreed to this before,</p> <p>22 but I want to make sure.</p> <p>23 MS. MILLER: No.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. That a weak statistically</p>

87 (Pages 342 to 345)

Christian Merlo, M.D., MPH

Page 346	Page 348
<p>1 significant result is inconsistent with a --</p> <p>2 for example, let's go back down here. Let's</p> <p>3 take -- see the Rosenblatt study, which was</p> <p>4 one that was done at your institution. That</p> <p>5 has -- was nonstatistically significant, in</p> <p>6 your view, and that is inconsistent with</p> <p>7 Cramer, which is -- shows a weak -- a weak</p> <p>8 statistically significant results.</p> <p>9 MS. MILLER: Objection. That</p> <p>10 mischaracterizes either his report or</p> <p>11 his testimony, whichever it is that</p> <p>12 you're characterizing.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. Doctor, is it your view that,</p> <p>15 using the example I just took, Cramer is</p> <p>16 inconsistent with Rosenblatt?</p> <p>17 A. Which Cramer?</p> <p>18 Q. Cramer 1982 and Rosenblatt</p> <p>19 1992.</p> <p>20 A. So Cramer 1982 shows a point</p> <p>21 estimate of 1.92, and the 95 percent</p> <p>22 confidence interval is 1.27 to 2.89.</p> <p>23 Rosenblatt, 1.27 --</p> <p>24 Q. No, Rosenblatt -- Rosenblatt</p> <p>25 1992, which is a hospital-based study.</p>	<p>1 was such a loaded question.</p> <p>2 MR. TISI: Oh, it is. It's a</p> <p>3 loaded -- it's a loaded headnote.</p> <p>4 THE WITNESS: So I'm not</p> <p>5 accusing anybody of anything.</p> <p>6 MS. MILLER: Objection.</p> <p>7 THE WITNESS: I'm just</p> <p>8 reporting what the medical evidence</p> <p>9 shows. And the medical evidence shows</p> <p>10 that there is inconsistency among</p> <p>11 similar study designs, inconsistency</p> <p>12 between hospital-based and</p> <p>13 population-based case controls,</p> <p>14 inconsistency among population</p> <p>15 case-controls, and inconsistency</p> <p>16 between cohort studies and case</p> <p>17 controls, all leading to</p> <p>18 inconsistency.</p> <p>19 I'm not accusing anyone of</p> <p>20 anything. I'm just reporting what's</p> <p>21 in the medical literature.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. So but you didn't just</p> <p>24 say they're inconsistent result. You say</p> <p>25 plaintiffs' experts fabricate consistency</p>
Page 347	Page 349
<p>1 A. Rosenblatt '92. Okay.</p> <p>2 Q. A hospital-based study.</p> <p>3 A. So that's a 1.7, with the</p> <p>4 95 percent confidence interval .7 to 3.9.</p> <p>5 Now, Cramer 1982 is</p> <p>6 statistically significant. Rosenblatt '92 --</p> <p>7 Cramer '82, statistically significant;</p> <p>8 Rosenblatt '92, not statistically</p> <p>9 significance.</p> <p>10 Q. And are those inconsistent?</p> <p>11 MS. MILLER: Objection.</p> <p>12 THE WITNESS: One is</p> <p>13 statistically significant, and one is</p> <p>14 not statistically significant. They</p> <p>15 are inconsistent with each other.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Okay. So and on page 44 and 45</p> <p>18 of your report, you criticize plaintiffs'</p> <p>19 experts. You say, "I would agree" -- you</p> <p>20 see, this is the part where you accuse them</p> <p>21 of fabrication. Page 44. "Plaintiffs'</p> <p>22 experts fabricate consistency by ignoring</p> <p>23 inconsistent studies," that heading.</p> <p>24 Do you see that?</p> <p>25 MS. MILLER: Objection. That</p>	<p>1 when there is none. Right?</p> <p>2 So that's -- I mean, maybe I'm</p> <p>3 splitting hairs, but that's a little bit more</p> <p>4 inflammatory than just simply saying, I find</p> <p>5 the studies inconsistent. Right?</p> <p>6 MS. MILLER: Objection.</p> <p>7 MR. LOCKE: Objection.</p> <p>8 THE WITNESS: I don't know. I</p> <p>9 don't know what your definition of</p> <p>10 inflammatory is.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. I think if somebody</p> <p>13 accused you of fabrication, you might be</p> <p>14 thinking that that might be inflammatory, but</p> <p>15 we'll see.</p> <p>16 MR. LOCKE: Objection.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Let's move on.</p> <p>19 You say plaintiffs' experts</p> <p>20 uniformly assert -- I'm sorry, uniformly</p> <p>21 assert consistent criterion has been</p> <p>22 satisfied, and then you go on to say, "I</p> <p>23 would agree with plaintiffs' experts that</p> <p>24 there's some consistencies among the study,</p> <p>25 but those consistencies are among the</p>

88 (Pages 346 to 349)

Christian Merlo, M.D., MPH

Page 350	Page 352
<p>1 hospital-based case-control studies and among 2 the large cohort studies showing no 3 statistically significant inconsistencies" -- 4 I'm sorry, "showing no association between 5 talc exposure and ovarian cancer. By 6 contrast, the inconsistencies between 7 hospital-based and population-based 8 case-control and within population-based 9 case-control studies." 10 Did I read that right? 11 Actually, let me -- I didn't 12 read it right. Let me read it again. 13 "I would agree with plaintiffs' 14 experts that there are some consistencies 15 between studies, but those consistencies are 16 among hospital-based case-control studies and 17 among large cohort studies showing no 18 statistically significant association between 19 talc exposure and ovarian cancer. By 20 contrast, there are inconsistencies between 21 hospital-based and population-based 22 case-control studies and within 23 population-based case-control studies." 24 Did I read that right? 25 A. Yes, sir.</p>	<p>1 here on -- in retyping this. 2 I did not highlight 3 statistically significant. So if you would 4 just do me a favor and take this pen and 5 circle "statistically significant" in the 6 middle of that paragraph, I'd appreciate 7 that. 8 MS. MILLER: Objection. 9 QUESTIONS BY MR. TISI: 10 Q. Go ahead, if you don't mind. 11 A. What do you want me to do? 12 Q. Just take statistically in -- 13 because in your document, you actually 14 highlight and italicize "statistically 15 significant" in your -- correct? 16 MS. MILLER: Huh? 17 QUESTIONS BY MR. TISI: 18 Q. In your -- on page 45, top 19 paragraph. 20 A. But that's not -- that's not 21 from page 45. This is page 44 from that 22 paragraph. 23 Q. Let me see. Maybe I gave you 24 the wrong one. 25 MS. MILLER: This is the</p>
Page 351	Page 353
<p>1 Q. Okay. And then you go on to 2 say -- and this is the statement that we 3 talked about before, the kind of the general 4 rule that you set out. It says, "It is 5 important to remember, contrary to the 6 suggestion of several of plaintiffs' experts 7 on page 45, that for this criteria to weigh 8 in favor of finding a causal relationship, 9 there must be consistency and statistically 10 significant associations. Consistency is -- 11 in relative risks that are not statistically 12 significant is not meaningful because that 13 sort of consistency does not provide any 14 degree of confidence that the claim of 15 association made by the study is more than 16 random chance." 17 Did I read that right? 18 A. That's correct. 19 (Merlo Exhibit 38 marked for 20 identification.) 21 QUESTIONS BY MR. TISI: 22 Q. Okay. Now, I'm going to have 23 that statement marked here as Exhibit 24 Number 38. But I'm going to do this, Doctor, 25 because I have to say that I made a mistake</p>	<p>1 paragraph -- 2 MR. TISI: I apologize. I'm 3 sorry, you're correct. It's 4 Exhibit 39. 5 (Merlo Exhibit 39 marked for 6 identification.) 7 MS. MILLER: So are we done 8 with this one? 9 MR. TISI: I'm just mark it. 10 It's the early part. We'll leave it 11 there. 12 QUESTIONS BY MR. TISI: 13 Q. This is 39. I'm sorry, Doctor. 14 A. That's okay. 15 Q. This is the paragraph on the 16 top of page 45. And I did not emphasize what 17 you emphasized, and I apologize for that. 18 You emphasized statistically 19 significant, and I didn't when I retyped 20 this. So if you would do me a favor and just 21 circle the words "statistically significant," 22 I'd appreciate it. 23 MS. MILLER: I'm going to 24 object to that. I think you should 25 circle it if you want it circled.</p>

89 (Pages 350 to 353)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 354</p> <p>1 THE WITNESS: It's mentioned 2 twice, so -- 3 QUESTIONS BY MR. TISI: 4 Q. Well, the one that you 5 highlighted in your report. 6 A. Looks like -- consistency and 7 statistically significant. This and this. 8 Q. And this is your rule that you 9 set out. It says, "Important to remember," 10 and this is a -- we talked about this earlier 11 in your deposition. Although there is no 12 citation for this, you agree that this is 13 your -- you believe that this is a generally 14 accepted principle in epidemiology? 15 A. It's a generally accepted 16 principle in epidemiology. 17 Q. Okay. Doctor, have you seen 18 references to the fact that statistical 19 significance is not the test of consistency? 20 A. You'd have to show me a 21 reference. 22 Q. Okay, let's do that. Could you 23 go -- can you pull out Exhibit 23, which is 24 the "From Association to Causation" chapter 25 that Johns Hopkins uses in courses there?</p>	<p style="text-align: right;">Page 356</p> <p>1 A. I do see that. 2 Q. Is there any mention of 3 statistical significance in this? 4 MS. MILLER: Objection. 5 THE WITNESS: There is not. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. But there's not a reference 9 saying that -- that if it's not there, the 10 opposite. 11 Q. Okay. Does it also talk about 12 there needs to be consistency among study 13 designs? 14 MS. MILLER: Objection. 15 QUESTIONS BY MR. TISI: 16 Q. This talks about among studies 17 but not study design, does it? 18 MS. MILLER: Objection. 19 THE WITNESS: It says, "If an 20 association observed, we would expect 21 it to be seen consistently within 22 subgroups of the population and in 23 different populations," which may 24 involve different studies and 25 different study designs.</p>
<p style="text-align: right;">Page 355</p> <p>1 It's the Gordis text. 2 Do you see that? 3 Do you have it in front of you? 4 A. I have Chapter 14, yes, 5 Exhibit 23. 6 Q. Can you go to page 251. On 7 page -- it talks about Replications of 8 Findings, which is the consistency issue, 9 right? 10 MS. MILLER: Objection. 11 THE WITNESS: I see where it 12 says "Replication of Findings." 13 QUESTIONS BY MR. TISI: 14 Q. And it says, "If the 15 relationship is causal, we would expect to 16 find consistency in different studies and in 17 different populations. Replication of 18 findings is particularly important in 19 epidemiology. If an association as observed, 20 we can also -- we would also expect it to be 21 seen consistently within subgroups of the 22 population and in different populations and 23 unless there is a clear reason to expect 24 different results." 25 Do you see that?</p>	<p style="text-align: right;">Page 357</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. But it doesn't say study 3 designs, does it? 4 MS. MILLER: Objection. 5 THE WITNESS: I don't think it 6 has to. That's inherent in the 7 statement. 8 QUESTIONS BY MR. TISI: 9 Q. Okay. Now, I previously asked 10 you whether you had done any independent 11 research on studies of talc and ovarian 12 cancer, and you said you had not. 13 Do you recall that? 14 MS. MILLER: Objection. 15 QUESTIONS BY MR. TISI: 16 Q. That was very early in the day. 17 MS. MILLER: Objection. 18 THE WITNESS: I don't recall. 19 I'm going to have to see it. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Have you done any 22 studies in talc and ovarian cancer? 23 A. What do you mean by "studies"? 24 Q. Have you done any observational 25 studies on talc and ovarian cancer?</p>

Christian Merlo, M.D., MPH

Page 358	Page 360
<p>1 A. I've reviewed the literature --</p> <p>2 Q. Have you done any studies?</p> <p>3 A. -- on the potential causal</p> <p>4 association between talcum powder and ovarian</p> <p>5 cancer. I've reviewed the literature.</p> <p>6 Q. Have you authored any studies</p> <p>7 on talc and ovarian cancer or designed any</p> <p>8 studies on talc and ovarian cancer?</p> <p>9 A. And I believe I told you no</p> <p>10 earlier on.</p> <p>11 Q. That was my question.</p> <p>12 Now, you mentioned in your</p> <p>13 report that there are seven hospital-based</p> <p>14 case-control studies examining the</p> <p>15 association between talc and ovarian cancer.</p> <p>16 A. Where did I say that?</p> <p>17 Q. It's in your chart, and you</p> <p>18 mentioned it several times today.</p> <p>19 MS. MILLER: You just said,</p> <p>20 this is in your report.</p> <p>21 THE WITNESS: You just said I</p> <p>22 wrote it in my report, so I just</p> <p>23 wanted to see where I said it.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Are there not seven</p>	<p>1 the Rosenblatt study, Exhibit Number 40.</p> <p>2 Did you actually read this</p> <p>3 study?</p> <p>4 A. I did.</p> <p>5 Q. Good.</p> <p>6 Let's go, so we don't have to</p> <p>7 spend a lot of time rereading it.</p> <p>8 A. I haven't memorized it, though.</p> <p>9 Q. Okay. One of the authors of</p> <p>10 this study, if you'll notice, is a guy we</p> <p>11 mentioned a couple times today, Dr. Szklo.</p> <p>12 He's the second author.</p> <p>13 A. Szklo, yes.</p> <p>14 Q. Szklo.</p> <p>15 He's at the school. He's a</p> <p>16 full professor there.</p> <p>17 Have you ever said, you know,</p> <p>18 "Doctor, there's a study done at our school.</p> <p>19 What do you think about this relationship?</p> <p>20 You've published on it."</p> <p>21 Have you gone and talked to</p> <p>22 him?</p> <p>23 A. I have not.</p> <p>24 MS. MILLER: Objection.</p> <p>25 MR. LOCKE: Objection.</p>
Page 359	Page 361
<p>1 observational -- seven hospital-based</p> <p>2 studies, Doctor?</p> <p>3 A. I have a chart here that has</p> <p>4 seven hospital-based case-control studies.</p> <p>5 Q. Okay. And one of them we just</p> <p>6 talked about, it was Rosenblatt, and it was</p> <p>7 done here at Johns Hopkins, was it not?</p> <p>8 A. I don't specifically recall.</p> <p>9 Q. Well, actually, you mention</p> <p>10 that on page 14 of your report. Go to</p> <p>11 page 14 of your report.</p> <p>12 You say, "Rosenblatt is a 1992</p> <p>13 reported hospital-based study evaluating</p> <p>14 fiber exposure generally with fiber defined</p> <p>15 as asbestos talc or fiberglass, et cetera,</p> <p>16 done in Johns Hopkins Hospital."</p> <p>17 Do you see that?</p> <p>18 A. A little bit before my time,</p> <p>19 1981 to 1985 --</p> <p>20 Q. Right.</p> <p>21 A. -- at Johns Hopkins.</p> <p>22 (Merlo Exhibit 40 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. All right. I'm like to attach</p>	<p>1 MS. MILLER: Give us time to</p> <p>2 object, Doctor.</p> <p>3 THE WITNESS: Okay. Sorry.</p> <p>4 I did my own independent</p> <p>5 search, and I evaluated the body of</p> <p>6 medical evidence.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. Now, if you go to -- I'm sorry.</p> <p>9 A. I did read this article, and I</p> <p>10 did see that -- recall now that I did see his</p> <p>11 name on there, but it did not interfere or</p> <p>12 cause me reflection to go talk to him about</p> <p>13 it because I was going to perform my own</p> <p>14 independent review.</p> <p>15 Q. Right.</p> <p>16 So you had on the chart -- on</p> <p>17 your chart, exhibit number -- do you have</p> <p>18 your chart in front of you? Exhibit 37?</p> <p>19 A. I have Exhibit 37, yes.</p> <p>20 Q. And I asked you before whether</p> <p>21 or not Rosenblatt was inconsistent with</p> <p>22 Cramer.</p> <p>23 Do you remember that?</p> <p>24 And you said yes?</p> <p>25 A. So if we're still -- which</p>

91 (Pages 358 to 361)

Christian Merlo, M.D., MPH

Page 362	Page 364
<p>1 Rosenblatt, again, are we talking about?</p> <p>2 Because there are two Rosenblatts.</p> <p>3 Q. 1992.</p> <p>4 A. Rosenblatt '92. I got it.</p> <p>5 Q. And Cramer 1982.</p> <p>6 A. Got it.</p> <p>7 Q. And I asked you the question,</p> <p>8 and you said that they were inconsistent.</p> <p>9 Well, let's see what Dr. Szklo</p> <p>10 says about this.</p> <p>11 Now, just to be clear,</p> <p>12 Rosenblatt is a hospital-based case-control</p> <p>13 study?</p> <p>14 A. Rosenblatt was a hospital-based</p> <p>15 case-control study, yes, that's correct.</p> <p>16 Q. And Cramer was a</p> <p>17 population-based case-control study?</p> <p>18 A. Cramer 1982 was a</p> <p>19 population-based case-control study.</p> <p>20 Q. Now, first, if you go to the</p> <p>21 study itself, if you go to the third page,</p> <p>22 page 22.</p> <p>23 A. Page 22, yes.</p> <p>24 Q. It says -- actually, the second</p> <p>25 column it says, "We found an increased</p>	<p>1 A. -- an odds ratio of 1 --</p> <p>2 Q. Okay.</p> <p>3 A. -- which is null.</p> <p>4 Q. And when you have talc, it's</p> <p>5 1.7, and when you have it directly applied to</p> <p>6 sanitary napkins, it was 4.8 -- do you see</p> <p>7 that? -- which was statistically significant.</p> <p>8 A. Statistically significant with</p> <p>9 a confidence interval of 1.3 to 17.8, a very,</p> <p>10 very wide range, and with also a proportion</p> <p>11 of missing -- of cases and controls with</p> <p>12 missing exposure.</p> <p>13 Q. But then he says something that</p> <p>14 addresses your point directly. It says,</p> <p>15 "This is" -- and I'm going to read the whole</p> <p>16 paragraph.</p> <p>17 MS. MILLER: Tell us where you</p> <p>18 are.</p> <p>19 MR. TISI: Yeah. Second</p> <p>20 column. It's beginning with "we</p> <p>21 found" on page 22.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. "We found an increased relative</p> <p>24 risk, 4.8 for talc use on sanitary napkins,</p> <p>25 with a smaller effect for genital bath</p>
Page 363	Page 365
<p>1 relative risk, 4.8, for talc use on sanitary</p> <p>2 napkins, with a smaller effect on genital</p> <p>3 bath talc exposure, relative risk 1.7."</p> <p>4 Do you see that?</p> <p>5 A. I do see that.</p> <p>6 Q. Can you tell me why it is you</p> <p>7 didn't refer to the talc on sanitary napkins'</p> <p>8 relative risk of 4.8, which was statistically</p> <p>9 significant?</p> <p>10 A. The point estimate that I took</p> <p>11 out of that was for genital talc exposure,</p> <p>12 which is a relative risk of 1.70.</p> <p>13 Q. All right. But genital talc</p> <p>14 exposure was defined as asbestos --</p> <p>15 asbestos -- I'm sorry, it was actually fiber</p> <p>16 exposure.</p> <p>17 In your report on page 15, you</p> <p>18 talk about it as being -- it's defined --</p> <p>19 A. Well, if you actually look at</p> <p>20 Table 3, the genital fiber use, yes/no, has</p> <p>21 an odds ratio of 1.0, and the 95 percent</p> <p>22 confidence interval is 0.2 to 4.0.</p> <p>23 So if we're just talking about</p> <p>24 genital fiber use, there's --</p> <p>25 Q. Okay.</p>	<p>1 exposure, 1.7."</p> <p>2 And that 1.7 was not</p> <p>3 statistically significant, correct?</p> <p>4 A. The 1.7 was not statistically</p> <p>5 significant.</p> <p>6 Q. Okay. He then says, "This is</p> <p>7 in accordance with the original finding of a</p> <p>8 significant increased risk for perineal talc</p> <p>9 exposure, relative risk 1.9, 95 percent</p> <p>10 confidence interval, 1.3 to 2.9, by Cramer,</p> <p>11 et al."</p> <p>12 And that's the Cramer article</p> <p>13 from 1982, correct?</p> <p>14 A. That's what it says.</p> <p>15 Q. Okay. And so he's saying his</p> <p>16 results are actually consistent with what</p> <p>17 Cramer found.</p> <p>18 A. But they're not.</p> <p>19 Q. Okay. But Dr. Szklo says that</p> <p>20 they are?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: If we're talking</p> <p>23 about consistency here between two</p> <p>24 studies and talking about statistical</p> <p>25 significance and consistency within</p>

92 (Pages 362 to 365)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 366</p> <p>1 statistical significance, they're not 2 consistent. 3 QUESTIONS BY MR. TISI: 4 Q. Okay. Because statistical 5 significance is never the test for 6 consistency, is it, Doctor? 7 And everybody from the 8 epidemiology textbooks to the American 9 Statistical Association says, don't do what 10 you did in this report, true? 11 MS. MILLER: Objection. 12 MR. LOCKE: Objection. 13 THE WITNESS: I don't even know 14 what that means, and I -- 15 QUESTIONS BY MR. TISI: 16 Q. Okay. 17 A. -- don't know what you mean by 18 everyone and -- 19 Q. Well, we're going to talk -- 20 A. -- who those different groups 21 are, so you'd have be very specific. 22 Q. We're going to be -- 23 A. It's a very big generalization. 24 Q. Well, you made a lot of 25 generalizations about what the epidemiology</p>	<p style="text-align: right;">Page 368</p> <p>1 talc fiber exposure may be associated with an 2 adverse event, but further study is needed." 3 Do you see that? 4 A. I do, and that's a very, very 5 general statement. There's a "suggest," 6 there's a "may," there's an "associated," 7 there's an "adverse effect." I don't even 8 know what that means. 9 Q. He never said it was 10 inconsistent, did he? He said, in fact, his 11 study -- this study is in accordance with the 12 original study. 13 MS. MILLER: Objection. 14 THE WITNESS: This statement 15 right here is not talking about -- is 16 not talking about consistency, this 17 results of our study. I don't know 18 why that has anything to do with 19 consistency. 20 QUESTIONS BY MR. TISI: 21 Q. Okay. Well, let's go to the 22 paragraph that does. 23 It says above, "We found an 24 increased, 4.8 for talc use on sanitary 25 napkins, with a smaller effect for genital</p>
<p style="text-align: right;">Page 367</p> <p>1 community thinks. 2 MR. LOCKE: Objection. 3 QUESTIONS BY MR. TISI: 4 Q. So I'm talking to you about 5 epidemiology textbooks. The American 6 Statistical Association says, you don't do 7 what you did here. 8 MS. MILLER: Objection. 9 MR. LOCKE: Objection. 10 QUESTIONS BY MR. TISI: 11 Q. Let me ask you this. He says 12 below, "The results of our study suggest that 13 genital talc fiber exposure may be associated 14 with an adverse event, but further study is 15 needed to determine if this relationship is 16 causal in nature from 1990 -- this 1992 17 study." 18 Correct? 19 A. Where are you reading that? 20 Q. The paragraph below. It says, 21 "The results of our study." Two paragraphs 22 down. 23 A. Okay. 24 Q. Okay. It says, "The results of 25 our study and others suggest that genital</p>	<p style="text-align: right;">Page 369</p> <p>1 bath talc exposure, relative risk, 1.7. This 2 is in accordance with the original finding of 3 a significant increased risk for perineal 4 talc exposure by Cramer, et al. Preliminary 5 findings from a Chinese talc study also 6 suggest the application of talc-containing 7 dusting powder and the risk of epithelial 8 ovarian cancer relative risk to be 1.9, with 9 a confidence interval of 1.1 to 13.8," which 10 is the Chen study on your list. "A 11 nonsignificant effect for genital talc 12 exposure on genital sanitary napkins or 13 underwear was detected in a study by Hartge, 14 relative risk 2.5, which was not 15 statistically significant. Whittemore, et 16 al., detected an increased relative risk 1.4, 17 P value greater than .05, for perineal 18 exposure. In a study of borderline ovarian 19 tumors, the increased risk was also observed 20 with talc exposure use on sanitary napkins, 21 relative risk 1.9 with a confidence interval 22 of .9 to 6.9." 23 This paragraph says all these 24 studies show an increased risk, true? 25 Including the last one that says an increased</p>

Christian Merlo, M.D., MPH

Page 370	Page 372
<p>1 risk was observed in a nonstatistically 2 significant study. 3 MS. MILLER: Objection. 4 MR. LOCKE: Objection. 5 THE WITNESS: This paragraph 6 does not say that there's an increased 7 risk in all these studies. 8 This paragraph says -- this 9 paragraph highlights that some studies 10 are statistically significant and 11 others are nonstatistically 12 significant. And that is not 13 consistent. 14 QUESTIONS BY MR. TISI: 15 Q. They say these are -- these 16 studies are in accordance, and you're saying 17 that that's inconsistent? 18 MS. MILLER: Objection. 19 THE WITNESS: That's not what 20 it says. 21 QUESTIONS BY MR. TISI: 22 Q. It says this study is in 23 accordance with the original finding of a 24 significant -- a significant increased risk 25 for perineal talc exposure, true? Does it</p>	<p>1 statement. It says "suggests," "may," 2 "associated adverse effect." I don't even 3 know what the adverse effect he's talking 4 about is. 5 Q. Well, how about the last -- 6 let's talk about the last paragraph. 7 "In summary" -- 8 MS. MILLER: The last paragraph 9 of what -- 10 MR. TISI: Of the study. 11 MS. MILLER: Oh, okay. 12 QUESTIONS BY MR. TISI: 13 Q. "In summary, our study shows 14 that the development of ovarian cancer may 15 be -- may be associated with genital fiber 16 exposure, especially talc on sanitary 17 napkins." 18 Do you see that? 19 A. I do. 20 And then it says, "Given its 21 small sample size and the potential selection 22 bias stemming from including patients in only 23 one hospital, further research needs to be 24 performed in order to confirm our findings." 25 And that is the importance of</p>
Page 371	Page 373
<p>1 not say that? 2 A. And what that sentence is 3 referring to is the sentence before that, 4 which is talking about an increased relative 5 risk for talc use on sanitary napkins, and 6 that's it. It's not in accordance -- 7 Q. No, that's not true. 8 A. It is. 9 Q. It says with a smaller effect 10 for genital bath talc exposure, relative risk 11 1.7. It includes both, does it not? 12 A. That relative risk is not 13 statistically significant. If they're 14 talking about the point estimate being over 15 1, that may be true, but this paragraph does 16 not say anything about consistency within 17 these studies. In fact, this highlights 18 inconsistency between all of these studies. 19 Q. Okay. Well, and so 20 Dr. Moyses -- Dr. Szklo is wrong when he says 21 this: "The results of our study and others 22 suggest that genital fiber exposure may be 23 associated with an adverse effect." 24 He's wrong when he says that? 25 A. That is such a general</p>	<p>1 consistency. And that first paragraph that 2 you highlighted demonstrates the lack of 3 consistency. 4 Q. Doctor, he's saying that this 5 study is further support of the hypothesis, 6 additional study needs to be done, but that 7 this shows that the development of ovarian 8 cancer may be associated with genital fiber 9 exposure. That's what he says. I'm reading 10 directly from the report. 11 MR. LOCKE: Objection. 12 THE WITNESS: And where are you 13 reading that? 14 QUESTIONS BY MR. TISI: 15 Q. "In summary, our study shows 16 that the development of ovarian cancer may be 17 associated with genital fiber exposure, 18 especially talc on sanitary napkins and 19 exposure to fibers in relatives." 20 He does say that, correct? 21 MS. MILLER: Objection. 22 THE WITNESS: He says, "Our 23 study shows that the development of 24 ovarian cancer may be associated." 25 "May be associated."</p>

Christian Merlo, M.D., MPH

Page 374	Page 376
<p>1 And then he also says -- and 2 I'll say this again -- "Given its 3 small sample size and the potential 4 for selection bias" -- 5 QUESTIONS BY MR. TISI: 6 Q. And he doesn't say this is 7 inconsistent, does he? He doesn't say, our 8 studies are opposite to. He doesn't say, our 9 studies are inconsistent with, does he? 10 MR. LOCKE: Objection. 11 MS. MILLER: Objection. 12 THE WITNESS: He doesn't say 13 they're inconsistent. He doesn't say 14 either. But they are inconsistent 15 with each other, because some are 16 showing a statistical significance and 17 some are not. 18 (Merlo Exhibit 41 marked for 19 identification.) 20 QUESTIONS BY MR. TISI: 21 Q. Let's go to another one. 22 A. They're inconsistent. 23 Q. Let's go to another one. 24 There's another one that you refer to. It's 25 the Tzonou study from Greece, the Tzonou</p>	<p>1 A. Can you just show me? I'm 2 sorry, I just didn't know where that was. 3 Okay. 4 Q. Does it not say, "The result of 5 the present study do not support the 6 association between talc and ovarian cancer 7 but given the overlapping range of the 8 confidence intervals, they are not 9 incompatible"? 10 MR. LOCKE: Objection. 11 THE WITNESS: I do see that 12 sentence, but I'm just trying to 13 figure out where that -- that that is 14 reference to. 15 QUESTIONS BY MR. TISI: 16 Q. Okay. Was it important to you 17 to figure out what that doctor meant by that? 18 The overlapping confidence intervals is 19 consistency, is it not? 20 MR. LOCKE: Objection. 21 THE WITNESS: I don't know what 22 you mean by overlapping confidence 23 intervals. 24 QUESTIONS BY MR. TISI: 25 Q. If confidence intervals overlap</p>
Page 375	Page 377
<p>1 study. I'm going to show you this one. This 2 is one you also read. 3 And this is another 4 hospital-based study, correct? 5 And this is the one on your 6 chart -- 7 MS. MILLER: I'm sorry, I took 8 yours. 9 MR. TISI: I'm sorry. 10 QUESTIONS BY MR. TISI: 11 Q. This is the one on your chart 12 that has a 1.05 with a confidence interval of 13 .28 to 3.98. 14 Do you see that? 15 A. I see on my chart 1.05, with a 16 95 confidence interval of .28 to 3.98. 17 Q. Let's look at what these 18 doctors say about this relationship. If you 19 go to page 409, second column, it says, "The 20 results of the present study do not support 21 an association between talc and ovarian 22 cancer but given the overlapping range in the 23 confidence intervals, they are not 24 incompatible with it." 25 True?</p>	<p>1 between studies and -- let's say at 1.2, 2 those are consistent. The confidence 3 intervals are consistent, correct? 4 MS. MILLER: Objection. 5 THE WITNESS: It depends. It 6 depends if you have three, eight, ten 7 studies that show 1.2, 1.3, their 8 confidence intervals overlap and those 9 are all statistically significant, 10 then those would be consistent. 11 However, if you have a point 12 estimate -- if you have several 13 studies that have point estimates of 14 1.2, 1.3, those are statistically 15 significant, and you have several 16 studies that have similar point 17 estimates but they're not 18 statistically significant, no, they 19 would be inconsistent with each other. 20 QUESTIONS BY MR. TISI: 21 Q. Even though the confidence 22 intervals overlap? 23 A. That's not really how you 24 approach consistency, in just looking at the 25 confidence intervals and seeing if they</p>

Christian Merlo, M.D., MPH

Page 378	Page 380
<p>1 overlap.</p> <p>2 Because the two studies, if</p> <p>3 we're talking about a consistent set, the</p> <p>4 studies would be statistically significant,</p> <p>5 and that would point towards consistency.</p> <p>6 Q. I'm going to like to show</p> <p>7 you -- have you seen a meta-analysis of the</p> <p>8 hospital-based studies at all?</p> <p>9 A. I did review some</p> <p>10 meta-analyses.</p> <p>11 Q. Did you review the</p> <p>12 meta-analyses of the hospital-based studies?</p> <p>13 A. I would have to look back at my</p> <p>14 report and see --</p> <p>15 Q. Let me see if I can show you</p> <p>16 the Berge study.</p> <p>17 A. -- which -- which had the</p> <p>18 hospital-based studies.</p> <p>19 Q. Let me show you the Berge</p> <p>20 study, which you've actually seen, correct?</p> <p>21 MS. MILLER: Can you show us,</p> <p>22 too?</p> <p>23 THE WITNESS: Okay.</p> <p>24 (Merlo Exhibit 48 marked for</p> <p>25 identification.)</p>	<p>1 significant for the hospital-based studies,</p> <p>2 correct?</p> <p>3 A. For -- that's what that</p> <p>4 suggests for those six studies.</p> <p>5 Q. Now, Doctor, just while we're</p> <p>6 at it here, and we're going to talk about</p> <p>7 the -- by the way, you didn't reference that</p> <p>8 in your report, did you, that there was a</p> <p>9 meta-analysis of the hospital-based studies</p> <p>10 that showed a statistically significant</p> <p>11 increased risk?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Can you ask that</p> <p>14 one more time?</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Yes.</p> <p>17 You didn't note that there was</p> <p>18 a meta-analysis of the hospital-based studies</p> <p>19 in the Berge study that showed a</p> <p>20 statistically significant increased risk, did</p> <p>21 you?</p> <p>22 MR. LOCKE: Objection.</p> <p>23 THE WITNESS: In the</p> <p>24 meta-analysis done by Berge, I did not</p> <p>25 reference that hospital-based</p>
Page 379	Page 381
<p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. If you go to the table on</p> <p>3 page 6 of 15.</p> <p>4 Do you see they have</p> <p>5 case-control studies and they have</p> <p>6 hospital-based control studies?</p> <p>7 Do you see that?</p> <p>8 A. I do see that.</p> <p>9 Q. Okay. See the relative risk of</p> <p>10 1.34?</p> <p>11 A. I do see 1.34.</p> <p>12 Q. See the confidence interval</p> <p>13 greater than 1, 1.16 to 1.51?</p> <p>14 A. I see 1.16 to 1.51.</p> <p>15 Q. What does that tell you,</p> <p>16 Doctor?</p> <p>17 MR. LOCKE: Objection.</p> <p>18 THE WITNESS: Well, it tells me</p> <p>19 that looking at these six case-control</p> <p>20 studies, the relative risk in however</p> <p>21 they lump these together was a 1.34,</p> <p>22 with a 95 percent confidence interval</p> <p>23 of 1.16 to 1.5 -- sorry, 1.51.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. And that's statistically</p>	<p>1 case-control study table right there.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. And that showed an increased</p> <p>4 risk?</p> <p>5 A. I would have to go through and</p> <p>6 look at the papers that were pulled for that</p> <p>7 because I have seven on my list, and there's</p> <p>8 six there.</p> <p>9 Q. Okay. But, of course, this</p> <p>10 study was published and yours wasn't. Your</p> <p>11 report has not been?</p> <p>12 MR. LOCKE: Objection.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: I didn't do a</p> <p>15 meta-analysis. I just gave a summary</p> <p>16 statement of the available</p> <p>17 hospital-based case controls, and</p> <p>18 they're all not statistically</p> <p>19 significant.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Right.</p> <p>22 And -- but when you combine</p> <p>23 them, because they were not powered to do it,</p> <p>24 they were small studies, because the</p> <p>25 confidence intervals were large -- you</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 382</p> <p>1 indicated that before. When you combine 2 them, you increase the power, right? 3 MR. LOCKE: Objection. 4 MS. MILLER: Objection. 5 THE WITNESS: You can -- 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. -- if the studies looked at the 9 same thing. 10 Q. Right. 11 A. If they looked at the same 12 measure of exposure. 13 Q. So when they combine them, it 14 increased the power. They show a 15 statistically significant results in the 16 Berge study, correct? 17 MS. MILLER: Objection. He 18 specifically said something different. 19 MR. TISI: You get to cross. 20 THE WITNESS: If, in fact, the 21 studies are measuring the same aspect 22 of the exposure, which there are 23 varying measures of exposure with -- 24 in all of the case-control studies, if 25 they're measuring the same thing, then</p>	<p style="text-align: right;">Page 384</p> <p>1 THE WITNESS: And I would have 2 to go through and see why there's only 3 six there and see what the measure of 4 risk was and whether or not that was 5 appropriate to even combine those. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. But you didn't do that, 8 and you didn't address this in your report? 9 MR. LOCKE: Objection. 10 THE WITNESS: So in looking at 11 this table now, I'm looking at the 12 hospital-based case-control studies, 13 and there's six of them, and the 14 relative risk is as you say. But 15 there is significant heterogeneity 16 within the studies, and so it may not 17 be appropriate to lump all of those 18 together. 19 And I believe that the authors 20 concluded that because of 21 heterogeneity, it did not support a 22 causal interpretation of the 23 association. 24 QUESTIONS BY MR. TISI: 25 Q. Doctor, let me ask you this:</p>
<p style="text-align: right;">Page 383</p> <p>1 it does add -- it does add more study 2 subjects, which increases -- it does 3 add more study subjects. 4 QUESTIONS BY MR. TISI: 5 Q. And it does increase the power? 6 MR. LOCKE: Objection. 7 QUESTIONS BY MR. TISI: 8 Q. To detect an association, 9 correct? 10 MR. LOCKE: Objection. 11 MS. MILLER: Objection. 12 THE WITNESS: That's not really 13 what power is for. Power is to say 14 that if you don't detect a certain 15 association, that you're not wrong 16 about that. That's what power's for. 17 QUESTIONS BY MR. TISI: 18 Q. Well, the original studies did 19 not detect a statistically significant 20 result, but when you combine them, they did, 21 true? 22 MS. MILLER: Objection. 23 MR. LOCKE: Objection. 24 MS. MILLER: No, that's not 25 what he said.</p>	<p style="text-align: right;">Page 385</p> <p>1 It also says at the top -- and if you look at 2 the abstract -- actually, the -- and I'll 3 represent to you that this study was actually 4 amended. The original study was amended a 5 year later, so this is the amended study. 6 It says, "This meta-analysis 7 resulted in a weak" -- second to the last 8 sentence -- "weak but statistically 9 significant association between genital talc 10 use and ovarian cancer, which appears to be 11 limited to serous carcinoma with the 12 suggestion of a dose response." 13 Do you see that? 14 MR. LOCKE: Objection. 15 THE WITNESS: That's in the 16 abstract? 17 QUESTIONS BY MR. TISI: 18 Q. Yes. 19 A. Can you read that again? 20 Q. Yeah. 21 Second to the last sentence. 22 It says, "The meta-analysis results in a weak 23 but statistically significant association 24 between genital talc -- genital use of talc 25 and ovarian cancer, which appears to be</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 386</p> <p>1 limited to serous carcinoma and suggests -- 2 with the suggestion of dose response." 3 Did I read that correctly? 4 A. You read that correctly. 5 Q. You don't note that in your 6 report, do you? 7 MR. LOCKE: Objection. 8 THE WITNESS: But the authors 9 also say in their concluding sentence, 10 "Several aspects of our study, 11 including heterogeneity of results 12 between case-control and cohort 13 studies, however, do not support a 14 causal interpretation of the 15 association." 16 QUESTIONS BY MR. TISI: 17 Q. I understand, Doctor. 18 I asked you whether I read the 19 prior sentence correctly about a dose 20 response, and you didn't address that in your 21 report, did you not? 22 MR. LOCKE: Objection. 23 MS. MILLER: Objection. 24 THE WITNESS: Well, let's look 25 at dose response then.</p>	<p style="text-align: right;">Page 388</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. The question is whether you did 3 or you didn't. 4 MS. MILLER: Please don't 5 interrupt the witness. 6 MR. TISI: No, he needs to 7 answer my questions. 8 MS. MILLER: He's answering 9 your questions as fully as he can -- 10 MR. TISI: My question is, I 11 know you -- 12 MS. MILLER: And now you're 13 interrupting me. 14 MR. TISI: I know you -- well, 15 because you're coaching. 16 QUESTIONS BY MR. TISI: 17 Q. Doctor, I know you discussed 18 the -- 19 MR. TISI: Your laughing is 20 really, really overwhelming. 21 MS. MILLER: You just accused 22 me of coaching the witness for saying 23 "please don't interrupt him." 24 MR. TISI: You are totally 25 coaching the witness. Don't interrupt</p>
<p style="text-align: right;">Page 387</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Let's look at -- yeah. You 3 didn't address it. I looked for it. I 4 didn't find it. 5 A. The only reason I'm looking at 6 this is because I did address dose response, 7 and I looked at all of the dose response 8 within all of the studies available. And in 9 order for Berge to talk about dose response, 10 the studies that involve a dose response have 11 to go in there. 12 And aside from one study, which 13 is Wu 2015, there is no dose response. 14 There's random curves, there's convex curves, 15 convey curves, in Booth, Wong, Cook, Mills, 16 Merritt, Gertig, Cramer, in all of those. So 17 actually I did. 18 Q. Okay. My question is -- 19 A. And there's no dose response. 20 Q. Did you address Berge's 21 analysis of that issue? 22 MS. MILLER: Objection. 23 THE WITNESS: There's no need 24 to because -- 25</p>	<p style="text-align: right;">Page 389</p> <p>1 him. He was saying X, Y and Z. It's 2 coaching. 3 MS. MILLER: Excuse me? I 4 said, "Please don't interrupt the 5 witness." 6 Where did I say he was saying 7 X, Y and Z? 8 QUESTIONS BY MR. TISI: 9 Q. Doctor -- 10 MS. MILLER: What are you even 11 talking about? 12 QUESTIONS BY MR. TISI: 13 Q. Doctor, did you address the 14 analysis done by Berge on the dose response 15 issue in your report? 16 You may have done the 17 underlying studies, but did you discuss 18 Berge's? 19 MR. LOCKE: Objection. 20 THE WITNESS: I actually am 21 trying to find where the -- where the 22 dose response is even discussed in 23 Berge. 24 QUESTIONS BY MR. TISI: 25 Q. Okay. I can help you with</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 390</p> <p>1 that.</p> <p>2 Have you actually seen this?</p> <p>3 This -- because there are two Berge</p> <p>4 publications. There was the original and</p> <p>5 there was an amended one. This is the</p> <p>6 amended one.</p> <p>7 Did counsel provide you with</p> <p>8 the amended one?</p> <p>9 A. Counsel didn't provide me with</p> <p>10 any articles.</p> <p>11 Q. Okay.</p> <p>12 A. I looked them up myself.</p> <p>13 Q. Did you find this one?</p> <p>14 A. Again, I don't have these</p> <p>15 memorized, so I don't know which is the first</p> <p>16 one or which is the second one.</p> <p>17 Q. This is the second one.</p> <p>18 MS. MILLER: Is there a</p> <p>19 question pending? I'm so sorry, I</p> <p>20 lost it.</p> <p>21 MR. TISI: Yes.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Did you see this -- have you --</p> <p>24 will you see the second -- the second Berge</p> <p>25 study?</p>	<p style="text-align: right;">Page 392</p> <p>1 it'll be.</p> <p>2 THE WITNESS: I don't know how</p> <p>3 you can say that this -- that I</p> <p>4 didn't -- that I looked at this one or</p> <p>5 the other one.</p> <p>6 MR. TISI: It'll be what it'll</p> <p>7 be. I will compare the citation, and</p> <p>8 it'll either be the one you looked at</p> <p>9 or not. Let's move on.</p> <p>10 THE WITNESS: Well, we can</p> <p>11 compare it right now.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. I want to go -- Doctor --</p> <p>14 A. I'm going to look to compare it</p> <p>15 right now.</p> <p>16 Q. Well, then you can do it off</p> <p>17 the record. I'm not doing it on the record.</p> <p>18 A. Well, then you can't say</p> <p>19 that -- that you can just assume that --</p> <p>20 Q. I'm not --</p> <p>21 A. -- I saw the first one and</p> <p>22 didn't see the second one.</p> <p>23 Q. Doctor, I'll look it up. You</p> <p>24 have the citation in the back of your</p> <p>25 references. I'll just look it up.</p>
<p style="text-align: right;">Page 391</p> <p>1 A. I may have had the second one</p> <p>2 or the first one. I don't know.</p> <p>3 Q. Okay.</p> <p>4 A. Because it's not --</p> <p>5 MS. MILLER: Can we check his</p> <p>6 references?</p> <p>7 MR. TISI: Well, no, I think</p> <p>8 the record will be -- the record will</p> <p>9 be that he didn't, so we'll just go</p> <p>10 on.</p> <p>11 THE WITNESS: No, I'm not</p> <p>12 saying that, because I --</p> <p>13 MR. TISI: No, I think the</p> <p>14 record will be that the study that you</p> <p>15 looked at was the original Berge study</p> <p>16 but not the amended one.</p> <p>17 THE WITNESS: Why do you say</p> <p>18 that?</p> <p>19 MR. TISI: Because you have a</p> <p>20 citation to it with a year and the</p> <p>21 publication.</p> <p>22 MS. MILLER: And the citation</p> <p>23 is to 2018, and this year is this?</p> <p>24 THE WITNESS: And this is 2018.</p> <p>25 MR. TISI: Okay. It'll be what</p>	<p style="text-align: right;">Page 393</p> <p>1 If you go to your chart here,</p> <p>2 exhibit -- that we marked as Exhibit</p> <p>3 Number 37 -- it's right in front of you,</p> <p>4 sir -- would you agree with me that of all</p> <p>5 the studies of whatever design, other than</p> <p>6 Hartge 1983, Hartge and Stewart 1994, and</p> <p>7 Gonzalez 2016, all -- every single one of</p> <p>8 these risk ratios or relative risks or hazard</p> <p>9 ratios is greater than 1?</p> <p>10 MS. MILLER: Objection.</p> <p>11 THE WITNESS: The point</p> <p>12 estimates in this -- in this chart,</p> <p>13 Hartge 1983, Hartge Stewart '94, and</p> <p>14 Gonzales are all below 1. The others</p> <p>15 are -- the point estimates are above</p> <p>16 1.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Okay. And so of the</p> <p>19 30-some-odd studies, all of them have -- all</p> <p>20 of these studies, 30 of 33 or whatever the</p> <p>21 number happens to be, other than three have a</p> <p>22 risk ratio, relative risk or hazard ratio,</p> <p>23 greater than 1?</p> <p>24 A. A point estimate greater than</p> <p>25 1.</p>

Christian Merlo, M.D., MPH

Page 394	Page 396
<p>1 Q. Greater than 1. 2 Would you look at the 3 confidence interval of the ones that have a 4 greater -- a point estimate greater than 1? 5 Would you agree that the 6 confidence intervals overlap for every one of 7 those studies at 1.2? 8 MS. MILLER: Objection. 9 THE WITNESS: I would have to 10 use a calculator to do that. 11 QUESTIONS BY MR. TISI: 12 Q. Well, all you have to do is 13 look at the -- all you have to look at is the 14 confidence interval, right? The confidence 15 interval? If it overlaps 1.2, then it's -- 16 then they're overlapping, right? 17 A. It's not how we use a 18 confidence interval, but if that's what -- if 19 that's the number that you want to say, but 20 that's not how -- 21 Q. They're all -- every single one 22 of these confidence intervals, with the 23 exception of the three that I just talked 24 about, overlap at 1.2. 25 A. For the purpose of this</p>	<p>1 every one, but they -- most of them do. 2 In fact, even if you look at 3 the cohort studies, with the exception of 4 Gonzalez, they include 1.25. 5 A. Okay. 6 Q. Is that true? 7 A. It looks like it, based on this 8 chart. 9 Q. Now, I provided Dr. Ballman -- 10 have you seen Dr. Ballman's exhibits? 11 A. Yes. 12 Q. Okay. I provided her with a 13 copy of your chart, which I will have marked 14 as Exhibit 42. Since you had time to look at 15 it, I'm going to ask you whether you agree 16 with her or not. 17 (Merlo Exhibit 42 marked for 18 identification.) 19 QUESTIONS BY MR. TISI: 20 Q. I asked her to highlight, to 21 circle, every -- I asked her to highlight 22 every -- in red, in pink, every result that 23 was greater than 1.0, and she did. 24 Do you see that? 25 MS. MILLER: Objection.</p>
Page 395	Page 397
<p>1 exercise, looking down that column, 2 95 percent confidence interval, and you want 3 me to say whether or not there's overlap at 4 1.2? 5 Q. Uh-huh. 6 A. And what was the other 7 qualification? 8 Q. None. 9 The vast majority of these 10 confidence intervals overlap at 1.2, true? 11 A. 1.2 is included in many of 12 these. 13 Q. The vast majority -- in fact 14 every one, with the exception of three that I 15 just mentioned? 16 A. Well, Cramer 1982 is 1.27. Wu 17 2015 is 1.27. 18 Q. Right. 19 A. That doesn't include 1.2. 20 Q. Okay. Okay. 1.2 or above. 21 A. Okay. 22 Q. Is that true? 23 A. That is true for that column. 24 Q. Okay. And in fact, most of 25 them have -- overlap at 1.25, correct? Not</p>	<p>1 MR. LOCKE: Objection. 2 THE WITNESS: What -- you're -- 3 what did she highlight? 4 QUESTIONS BY MR. TISI: 5 Q. Every result that had a risk 6 ratio greater than 1.0, and she highlighted 7 that in pink. 8 A. And you're talking about the 9 point estimate? 10 Q. The point estimate, correct. 11 MR. LOCKE: I'm going to object 12 for the same reasons we did during her 13 deposition. 14 MR. TISI: Okay. 15 QUESTIONS BY MR. TISI: 16 Q. Do you see that? 17 A. That's what it looks like. 18 Q. Okay. And she circled every 19 point estimate -- she circled every 20 confidence interval that included 1.2, which 21 is a 20 percent increase, correct? 22 MR. LOCKE: Same objection. 23 MS. MILLER: Objection. 24 QUESTIONS BY MR. TISI: 25 Q. Do you see that, and do you</p>

100 (Pages 394 to 397)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 398</p> <p>1 disagree with that?</p> <p>2 MS. MILLER: I'm going to</p> <p>3 object. I don't understand how you</p> <p>4 disagree with circling, and also --</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Do you --</p> <p>7 MS. MILLER: -- this is kind of</p> <p>8 illegible.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. Do you agree --</p> <p>11 MR. TISI: It's very legible to</p> <p>12 me, Counsel, but you can coach your</p> <p>13 witness if you'd like. I can read it</p> <p>14 very carefully. Very well.</p> <p>15 THE WITNESS: I see circles in</p> <p>16 the 95 percent confidence interval,</p> <p>17 and if you're asking if those circles</p> <p>18 include a range that includes 1.2 in</p> <p>19 that 95 percent confidence interval,</p> <p>20 that's what it appears to show.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. And then I asked her to</p> <p>23 highlight in blue those that included 1.25,</p> <p>24 and she did that as well.</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 400</p> <p>1 she appears to have done what you've</p> <p>2 asked her to do --</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Okay.</p> <p>5 A. -- and circled.</p> <p>6 Q. And if asked to do the same</p> <p>7 thing, you would have done the same circling</p> <p>8 and the same highlighting?</p> <p>9 MR. LOCKE: Objection.</p> <p>10 THE WITNESS: If you asked me</p> <p>11 the same questions, it appears that</p> <p>12 she followed your directions</p> <p>13 appropriately.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Okay. Now, I'm going to show</p> <p>16 you what -- a textbook. It's already been</p> <p>17 marked as Exhibit Number 32.</p> <p>18 Can you pull that out, please?</p> <p>19 That's the Rothman textbook.</p> <p>20 A. 32?</p> <p>21 Q. Uh-huh. I have another copy in</p> <p>22 case anybody wants it because I don't really</p> <p>23 need paper. You can have it if you'd like.</p> <p>24 MS. MILLER: Okay. Instead of</p> <p>25 making us go through our pile.</p>
<p style="text-align: right;">Page 399</p> <p>1 MR. LOCKE: Objection.</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: The blue is a</p> <p>4 little bit difficult to make out.</p> <p>5 There's purple.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Well, purple is the -- it's</p> <p>8 blue and red. We didn't use a purple marker.</p> <p>9 A. And so what was the question?</p> <p>10 Q. Those were the ones that</p> <p>11 included 1.25 in the confidence interval.</p> <p>12 A. So it looks like this exercise</p> <p>13 does have a blue mark to those values that</p> <p>14 would include a 1.25 within the confidence</p> <p>15 interval.</p> <p>16 Q. And so in terms of we can</p> <p>17 disagree with the significance of that, you</p> <p>18 agree that with the interpretation that she</p> <p>19 had about risk ratios greater than 1, the</p> <p>20 ones that are greater than 1.2 -- or they</p> <p>21 included 1.2 and the ones that included 1.25?</p> <p>22 MS. MILLER: Objection.</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: For the purposes</p> <p>25 of you asking her what to highlight,</p>	<p style="text-align: right;">Page 401</p> <p>1 Thanks.</p> <p>2 MR. TISI: Yeah.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Do you have it in front of you?</p> <p>5 A. I have Modern Epidemiology.</p> <p>6 Q. Okay. If you look at the</p> <p>7 consistency prong -- we've looked at the</p> <p>8 strength prong before -- and it's on page 26</p> <p>9 of 30.</p> <p>10 A. Okay.</p> <p>11 Q. Okay. And I'm going to read</p> <p>12 the paragraph and see whether you agree with</p> <p>13 it or not.</p> <p>14 In this textbook Dr. Rothman</p> <p>15 says --</p> <p>16 A. I'm sorry, where are you</p> <p>17 reading from?</p> <p>18 Q. The second paragraph under</p> <p>19 Consistency. This is the consistency prong.</p> <p>20 "One mistake in implementing</p> <p>21 the consistency" --</p> <p>22 A. But where is this in the paper?</p> <p>23 I'm not seeing it. I see the second</p> <p>24 paragraph.</p> <p>25 Q. "One mistake." It says -- it</p>

101 (Pages 398 to 401)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 402</p> <p>1 starts with "one mistake." 2 Do you see it? 3 A. I see it now. 4 Q. Okay. "One mistake in 5 implementing the consistency criterion is so 6 common it deserves special mention. It is 7 sometimes claimed that a literature or set of 8 results is inconsistent simply because some 9 results are statistically significant and 10 some are not. This sort of evaluation is 11 completely fallacious, even if one accepts 12 the use of statistical -- the use of 13 significance testing methods." 14 Did I read that correctly? 15 MR. LOCKE: Objection. 16 MS. MILLER: Objection. 17 MR. LOCKE: And to the 18 characterization of this as a 19 textbook. 20 THE WITNESS: I see that 21 statement on this page. 22 QUESTIONS BY MR. TISI: 23 Q. You can pull the textbook out 24 so I don't have to, like, deal with that kind 25 of objection.</p>	<p style="text-align: right;">Page 404</p> <p>1 this instance where there are several 2 different kinds of study designs -- there's 3 consistency within study results. There's 4 consistency within hospital-based 5 case-controls. There's consistency in 6 nonsignificant -- nonsignificant results. 7 There's inconsistency in 8 population-based case-control studies where 9 some showed statistical significance, some 10 don't. There's also consistency within 11 cohort studies where there's a consistent 12 nonstatistically significance. 13 So there's consistency and 14 there's inconsistency. And just to divide it 15 up simply the way that Dr. Rothman says here 16 is too general because there are very 17 specific instances that need to be considered 18 before just agreeing or disagreeing to that 19 statement. 20 (Merlo Exhibit 43 marked for 21 identification.) 22 QUESTIONS BY MR. TISI: 23 Q. Okay. Let me look at Dr. -- 24 what Dr. Oleckno says about it. Here's 25 Exhibit Number 43, which is also from the</p>
<p style="text-align: right;">Page 403</p> <p>1 MR. LOCKE: Well, it's a 2 portion of a book. 3 MR. TISI: Okay. Okay, Tom. 4 QUESTIONS BY MR. TISI: 5 Q. The chapter in a textbook. 6 That's exactly what you did, right? 7 A. I'm sorry? 8 Q. Do you agree with that 9 statement? 10 A. Do I agree with the statement? 11 Q. "One mistake in implementing 12 the consistency criterion is so common that 13 it deserves special attention. It is 14 sometimes claimed that a literature or set of 15 results is inconsistent simply because some 16 results are statistically significant and 17 some are not. That sort of evaluation is 18 completely fallacious, even if one accepts 19 the use of significance testing methods." 20 Did I read that correctly? 21 A. Yes, you did. 22 Q. Do you agree with that? 23 A. I would say it depends, and 24 I'll tell you why. Because it's a very 25 general statement. And if we're talking in</p>	<p style="text-align: right;">Page 405</p> <p>1 Oleckno textbook that you referred to in your 2 report. 3 And in the chapter -- 4 MS. MILLER: This appears to be 5 pages 131, 173 and 174 -- 6 MR. TISI: Correct. 7 MS. MILLER: -- so I'm going to 8 have the same objection. 9 MR. TISI: Fine. 10 MS. MILLER: This just pulls 11 things out of context rather than 12 including an inherent thing. I don't 13 know -- 14 MR. TISI: I know you don't 15 know. 16 MS. MILLER: -- what's between 17 pages 131 -- 18 MR. TISI: I know you don't 19 know, Counsel. 20 MS. MILLER: -- and 173 -- 21 MR. TISI: Objection. 22 MS. MILLER: -- and what occurs 23 after page 175. 24 MR. TISI: "Objection" is fine. 25 THE WITNESS: Can I take a</p>

102 (Pages 402 to 405)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 406</p> <p>1 favor?</p> <p>2 MR. TISI: Yeah.</p> <p>3 THE WITNESS: Can we take a</p> <p>4 little -- I just need to use the</p> <p>5 restroom.</p> <p>6 MR. TISI: Absolutely.</p> <p>7 THE WITNESS: Would that be</p> <p>8 okay?</p> <p>9 MR. TISI: Absolutely.</p> <p>10 THE WITNESS: All right.</p> <p>11 Thanks.</p> <p>12 VIDEOGRAPHER: The time is</p> <p>13 4:20 p.m., and we're going off the</p> <p>14 record.</p> <p>15 (Off the record at 4:20 p.m.)</p> <p>16 VIDEOGRAPHER: The time is</p> <p>17 4:32 p.m., and we are back on the</p> <p>18 record.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. If you go to page 174 of</p> <p>21 Exhibit 43, the Oleckno textbook, there's a</p> <p>22 bullet point talking about statistical</p> <p>23 significance. I gave it to you as the last</p> <p>24 document we gave you.</p> <p>25 A. Sorry, it was not in front of</p>	<p style="text-align: right;">Page 408</p> <p>1 A. I do see where that's said.</p> <p>2 Q. And that's correct, right?</p> <p>3 A. That's correct.</p> <p>4 Q. All right. "Conversely, P</p> <p>5 greater than .05 indicates that the observed</p> <p>6 measure of association is probably due to</p> <p>7 chance alone and hence not statistically</p> <p>8 significant."</p> <p>9 Correct? Do you see that?</p> <p>10 A. I do see that, correct.</p> <p>11 Q. Okay. "Statistical</p> <p>12 significance does not indicate the strength</p> <p>13 of an association, nor does it reveal its</p> <p>14 practical significance. For a number of</p> <p>15 reasons, most epidemiologists prefer to use</p> <p>16 confidence intervals rather than</p> <p>17 significant -- significance testing. For one</p> <p>18 thing, these provide more information than</p> <p>19 significance testing."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. And do you agree with that?</p> <p>23 A. So there's a lot of statements</p> <p>24 there.</p> <p>25 Q. The last sentence, the last two</p>
<p style="text-align: right;">Page 407</p> <p>1 me. I got it.</p> <p>2 Q. Okay. Go to page 174.</p> <p>3 A. This is a four-page summary of</p> <p>4 the textbook?</p> <p>5 Q. No, it's not a four-page</p> <p>6 summary of the textbook, Doctor. It is a</p> <p>7 page out of the textbook where he bullet</p> <p>8 points, and this is the point where he talks</p> <p>9 about statistical significance and</p> <p>10 significance testing.</p> <p>11 It says here, "Measures of</p> <p>12 association may be tested for statistical</p> <p>13 significance, i.e., if they significantly</p> <p>14 different {sic} from 1.0 for measures based</p> <p>15 on relative comparisons or significantly</p> <p>16 different from .0 for measures based on</p> <p>17 absolute comparisons. Statistical</p> <p>18 significance is rooted in hypothesis testing</p> <p>19 and is measured by the P value. Generally, P</p> <p>20 .05 indicates that an observed measure of</p> <p>21 association is unlikely to be due to chance</p> <p>22 alone based upon the assumption that there is</p> <p>23 no real association. Thus, it is considered</p> <p>24 statistically significant."</p> <p>25 You with me so far?</p>	<p style="text-align: right;">Page 409</p> <p>1 sentences I'm talking about.</p> <p>2 A. "For a number of reasons, most</p> <p>3 epidemiologists prefer to use confidence</p> <p>4 intervals rather than significance testing.</p> <p>5 For one thing, these provide more information</p> <p>6 than statistic -- significant testing."</p> <p>7 So it's an -- that's an</p> <p>8 important thing to consider, and I think we</p> <p>9 have to remember that statistical</p> <p>10 significance, a P value of less than .05,</p> <p>11 will give a confidence interval that does</p> <p>12 not -- that -- so if you have a statistically</p> <p>13 significant result, meaning that the P value</p> <p>14 is less than .05, then if you're looking at a</p> <p>15 measure of risk, then your confidence</p> <p>16 interval will not include 1.</p> <p>17 So they're not saying the</p> <p>18 same -- they're not saying different things.</p> <p>19 If your -- if your confidence interval does</p> <p>20 not include 1, then you're going to have a</p> <p>21 statistically significant result.</p> <p>22 The reason for looking at the</p> <p>23 confidence interval is because that gives you</p> <p>24 more information about the study. If the</p> <p>25 confidence interval is really, really tight,</p>

103 (Pages 406 to 409)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 410</p> <p>1 that means your measurement is really good or 2 your study sample is really, really big. 3 But you're not going to have a 4 statistically significant result if the 5 confidence interval crosses 1. It will be 6 statistically insignificant. 7 So dividing these things up is 8 not how this is meant to mean. What this 9 means is that the confidence interval just 10 gives you a little bit more information, but 11 they're not any different than each other. 12 It's the same thing. 13 (Merlo Exhibit 44 marked for 14 identification.) 15 QUESTIONS BY MR. TISI: 16 Q. All right. Doctor, I'm going 17 to show you what the American Statistical 18 Association says about this issue. I'm 19 attaching this as Exhibit Number 44. 20 I assume you've seen if you 21 read Dr. Ballman's testimony, because I think 22 it came out a couple of days before her 23 testimony. 24 A. Okay. 25 Q. I assume you've read this, sir?</p>	<p style="text-align: right;">Page 412</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. So underneath -- on page 2, it 3 says, "Pervasive problem." And you 4 understand the American Statistical 5 Association published 42 articles in one 6 journal relating to this issue? 7 A. I have no idea what the 8 American association -- what was it called? 9 Q. Statistical association? 10 A. The American Statistical 11 Association, that's not something I follow, 12 so it's not -- I would have no idea whether 13 they published 42 articles or -- 14 Q. That's a good point. 15 What epidemiology journals do 16 you actually get? You mentioned the American 17 Epidemiology -- the American Epidemiology. 18 Any others that you get? 19 A. So I don't subscribe to 20 journals because we all -- we get them 21 through our Welch Library. We have access to 22 pretty much every journal available. And so 23 there are a number of epidemiologic journals 24 within the Welch Library that I have access 25 to.</p>
<p style="text-align: right;">Page 411</p> <p>1 A. I have looked this over, yes. 2 Q. It says -- under the section it 3 says, "Retire Statistical Significance." 4 That's the title of the -- of the article. 5 Retire? 6 A. I don't have that, actually. I 7 have "Sciences Rise Up Against Statistical 8 Significance." 9 Q. All right. Well, okay. I have 10 a different version. 11 MS. MILLER: Retire is nature. 12 THE WITNESS: And then I have 13 "Comment." So this is a comment. 14 QUESTIONS BY MR. TISI: 15 Q. Right. Correct. 16 A. Not a study. 17 Q. Right. I understand. 18 Your report is a comment, 19 right? 20 MR. LOCKE: Objection. 21 MS. MILLER: Objection. 22 THE WITNESS: My report is a 23 conglomeration of my opinions based on 24 the medical evidence. 25</p>	<p style="text-align: right;">Page 413</p> <p>1 Q. Which ones do you get? Which 2 one do you look at? 3 A. It would depend on the 4 situation. It would depend on the 5 investigation that I'm undertaking. 6 Q. Okay. Do you know who Sander 7 Greenland is? 8 A. I do not. 9 Q. Okay. So on page 2 of this 10 document, it says, "Let's be clear about what 11 must stop. We should never conclude that 12 there is no difference or no association just 13 because a P value is larger than the 14 threshold, such as P .05 or equivalent, 15 because confidence interval includes zero. 16 Neither should we conclude that two studies 17 conflict because one had a statistically 18 significant result and the other did not. 19 These errors waste research efforts and 20 misinform policy decisions." 21 Do you see that? 22 A. I do. 23 Q. Okay. I assume you disagree 24 with that given what you said before? 25 A. Again, I think it's going to</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 414</p> <p>1 depend, and the reason why I say it's going</p> <p>2 to depend is because two studies may be</p> <p>3 inherently different. One study may have a</p> <p>4 very good study design and one study may have</p> <p>5 a poor design. One study may adjust for bias</p> <p>6 and confounding; one study may not.</p> <p>7 And this is a very, very</p> <p>8 generalized statement that can either be</p> <p>9 agreed or disagreed with because of those.</p> <p>10 Q. Okay. Doctor, I'm going to</p> <p>11 show you a -- can you please take out the</p> <p>12 article about misconceptions again, the</p> <p>13 Rothman review which I -- you -- Exhibit</p> <p>14 Number 28?</p> <p>15 A. Exhibit 28?</p> <p>16 Q. Uh-huh.</p> <p>17 A. Okay. I have it.</p> <p>18 Q. Misconception number 6, 1063.</p> <p>19 Can you read it for the record, please?</p> <p>20 A. Misconception -- which one?</p> <p>21 Q. 6.</p> <p>22 A. 6. Okay.</p> <p>23 "Misconception 6. Significant</p> <p>24 testing is useful and important for the</p> <p>25 interpretation of data."</p>	<p style="text-align: right;">Page 416</p> <p>1 it depends, because it depends on the study</p> <p>2 design. It depends on whether the</p> <p>3 researchers decided to set up their study</p> <p>4 well and properly control for bias, properly</p> <p>5 adjust for potential for confounding, analyze</p> <p>6 the results correctly. So all of those</p> <p>7 factors have to -- have to come into balance.</p> <p>8 And the interesting thing about</p> <p>9 this paper is it's published in the Journal</p> <p>10 of General Internal Medicine. And if he's an</p> <p>11 epidemiologist and has these very important</p> <p>12 misconceptions that he's trying to bring</p> <p>13 forward in the epidemiology community, I'm</p> <p>14 not sure why this wasn't published in an</p> <p>15 epidemiology journal.</p> <p>16 Q. Actually, in all fairness,</p> <p>17 Doctor, I could have chosen dozens of</p> <p>18 articles where Dr. Rothman makes the same,</p> <p>19 including in his textbook. He has been very</p> <p>20 adamant about this. So, I mean, you may not</p> <p>21 understand it, but he has written about this</p> <p>22 a lot.</p> <p>23 So let me -- you made a</p> <p>24 comment --</p> <p>25 MS. MILLER: We're going to</p>
<p style="text-align: right;">Page 415</p> <p>1 Q. And does it also say that -- on</p> <p>2 the second column, second paragraph,</p> <p>3 "Significant tests are a poor classification</p> <p>4 scheme for study results. Strong effects may</p> <p>5 be incorrectly interpreted as null findings</p> <p>6 because the author" --</p> <p>7 A. I'm sorry to interrupt. Where</p> <p>8 are you?</p> <p>9 Q. Second paragraph.</p> <p>10 A. Thank you.</p> <p>11 Q. On the right-hand side.</p> <p>12 A. I see it.</p> <p>13 Q. "Significant tests are a poor</p> <p>14 classification scheme for study results.</p> <p>15 Strong effects may be incorrectly interpreted</p> <p>16 as null findings because the authors</p> <p>17 fallaciously interpret lack of statistical</p> <p>18 significance or imply lack of effect or weak</p> <p>19 effects may be incorrectly interpreted as</p> <p>20 important because they are statistically</p> <p>21 significant."</p> <p>22 Do you see that?</p> <p>23 A. I do see that.</p> <p>24 Q. Do you agree with that?</p> <p>25 A. So again, I'm just going to say</p>	<p style="text-align: right;">Page 417</p> <p>1 have to object to that speech and move</p> <p>2 to strike that speech for the record.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. You made a comment, and I</p> <p>5 really have to push back on it.</p> <p>6 Let's go to the conclusion --</p> <p>7 A. Are you asking me if I don't</p> <p>8 understand it?</p> <p>9 Q. Do you not -- do you not -- do</p> <p>10 you understand it?</p> <p>11 A. Understand what?</p> <p>12 MS. MILLER: Objection.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. I don't understand what your</p> <p>15 question is.</p> <p>16 MS. SHARKO: You don't have to</p> <p>17 respond to the speeches, Doctor.</p> <p>18 MS. MILLER: Yeah, just let it</p> <p>19 go.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Doctor, if you go to the</p> <p>22 conclusion in this thing, he says -- he makes</p> <p>23 the following statement: "It is easy to</p> <p>24 declare that the result is not statistically</p> <p>25 significant, falsely implying that there is</p>

105 (Pages 414 to 417)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 418</p> <p>1 no indication of an association, rather than</p> <p>2 considering it the quantitative --</p> <p>3 quantitatively the range of associations that</p> <p>4 the data actually support."</p> <p>5 Do you see that?</p> <p>6 A. I do see that sentence.</p> <p>7 Q. Okay. And what he's talking</p> <p>8 about, the range of associations, is</p> <p>9 expressed by the confidence interval; is that</p> <p>10 correct?</p> <p>11 A. I don't know what he's</p> <p>12 referring to there.</p> <p>13 Q. Okay.</p> <p>14 A. But if he's talking about a</p> <p>15 nonstatistically significant result, then the</p> <p>16 confidence interval will include 1.</p> <p>17 (Merlo Exhibit 21 marked for</p> <p>18 identification.)</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. Doctor, I want to go</p> <p>21 back for a moment to the -- we were talking</p> <p>22 about the hospital-based studies and the</p> <p>23 heterogeneity, and we talked about Berge, and</p> <p>24 I want to talk about Penninkilampi for a</p> <p>25 moment.</p>	<p style="text-align: right;">Page 420</p> <p>1 A. Mucinous. Which ones?</p> <p>2 Mucinous, invasive mucinous, borderline?</p> <p>3 Q. Uh-huh.</p> <p>4 A. Yeah, with much -- a much lower</p> <p>5 number of studies that looked at that.</p> <p>6 Q. Would any bias or recall bias</p> <p>7 or confounding have -- what would that --</p> <p>8 what would explain that there would be a</p> <p>9 difference between serous tumors and</p> <p>10 nonserous tumors?</p> <p>11 Because I assume there would be</p> <p>12 no reason for a woman to recall exposure to</p> <p>13 one and not the other.</p> <p>14 MS. MILLER: Objection.</p> <p>15 Mischaracterizes this table, among</p> <p>16 other problems.</p> <p>17 THE WITNESS: I'm not sure what</p> <p>18 you're asking.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Okay. Let's go on.</p> <p>21 On the qualitative data</p> <p>22 synthesis on page -- on the right-hand</p> <p>23 column, at the bottom of the second paragraph</p> <p>24 it says, "The only outcome" -- it talks about</p> <p>25 the three cohort studies.</p>
<p style="text-align: right;">Page 419</p> <p>1 I'll show the Penninkilampi</p> <p>2 study which you reviewed in your report.</p> <p>3 A. Thank you.</p> <p>4 Q. And that's exhibit number --</p> <p>5 Exhibit Number 21.</p> <p>6 You've seen this study before?</p> <p>7 A. Yes, I have.</p> <p>8 Q. First of all, I'm going like</p> <p>9 you to go to page 200 -- to page 44, please.</p> <p>10 It's the one with the table on it.</p> <p>11 A. 44, yes.</p> <p>12 Q. Now, it showed -- on the</p> <p>13 Table 1 it shows serous invasive and serous</p> <p>14 borderline tumors having a statistically</p> <p>15 significant elevated risk of 1.32 and 1.39</p> <p>16 respectively, correct?</p> <p>17 A. Serous invasive, serous</p> <p>18 borderline, 1.32, 1.39.</p> <p>19 Q. Okay. And this is a</p> <p>20 meta-analysis, true?</p> <p>21 A. This is a meta-analysis.</p> <p>22 Q. Okay. Now it does not show the</p> <p>23 same for mucinous, mucinous invasive, et</p> <p>24 cetera, right? It shows that they're not</p> <p>25 statistically significant?</p>	<p style="text-align: right;">Page 421</p> <p>1 "The only outcome reported in</p> <p>2 all three studies was any perineal talc use,</p> <p>3 hence the available data from prospective</p> <p>4 studies was limited."</p> <p>5 Do you see that?</p> <p>6 A. Can you point me to where</p> <p>7 you're reading?</p> <p>8 Q. (Indicating.)</p> <p>9 MS. MILLER: So it's the third</p> <p>10 to the last paragraph, the last</p> <p>11 sentence? Is that where you are?</p> <p>12 MR. TISI: It's the second</p> <p>13 paragraph on the right-hand side.</p> <p>14 THE WITNESS: The last sentence</p> <p>15 of the second paragraph?</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. The last sentence.</p> <p>18 "The only outcome reported in</p> <p>19 all three core studies was any perineal talc</p> <p>20 use." And that would be irrespective of</p> <p>21 duration, frequency, et cetera, right?</p> <p>22 A. That would refer to any</p> <p>23 perineal talc use if they're combined</p> <p>24 together.</p> <p>25 Q. Right.</p>

106 (Pages 418 to 421)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 422</p> <p>1 And there -- so he indicated</p> <p>2 that the available data from the prospective</p> <p>3 studies, meaning the cohort studies, was</p> <p>4 limited, true? It's what he says?</p> <p>5 A. In combining them it's limited,</p> <p>6 because the cohort studies may have not</p> <p>7 collected the same data about talc exposure.</p> <p>8 Q. Okay. It also says, "A</p> <p>9 subgroup analysis related to study population</p> <p>10 setting, i.e., hospitals or general</p> <p>11 population, was performed for any perineal</p> <p>12 use application."</p> <p>13 Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And the conclusion was, "There</p> <p>16 was no difference between the pooled results</p> <p>17 for hospital-based and population studies,</p> <p>18 OR, 1.22 versus 1.33 respectively."</p> <p>19 Do you see that?</p> <p>20 A. I do see that sentence, but I</p> <p>21 need see what that's referring to, what table</p> <p>22 and where that's coming from.</p> <p>23 Q. Well, have you reviewed this</p> <p>24 before?</p> <p>25 A. I have. I just haven't</p>	<p style="text-align: right;">Page 424</p> <p>1 interval of 1.01 to 1.55, heterogeneity, .33.</p> <p>2 Do you see that?</p> <p>3 A. Which line is that?</p> <p>4 Q. Under Types of Ovarian Cancer,</p> <p>5 Doctor. Right here.</p> <p>6 A. I see that.</p> <p>7 Q. Let's read what he says in</p> <p>8 conclusion. The conclusion that</p> <p>9 Dr. Penninkilampi reaches when he did his</p> <p>10 meta-analysis says -- and this is</p> <p>11 January 2018. "The results of this review</p> <p>12 indicate that perineal talc is associated</p> <p>13 with a 24 to 39 percent increased risk of</p> <p>14 ovarian cancer. While the case-control</p> <p>15 studies are prone to recall bias, especially</p> <p>16 with intense media attention following the</p> <p>17 commencement of a litigation in 2014, the</p> <p>18 confirmation of an association in cohort</p> <p>19 studies between perineal talc use and serous</p> <p>20 ovarian cancer is suggestive of a causal</p> <p>21 association."</p> <p>22 Do you see that?</p> <p>23 A. I do see that; however,</p> <p>24 Penninkilampi --</p> <p>25 Q. I didn't ask you a question. I</p>
<p style="text-align: right;">Page 423</p> <p>1 memorized it. There's a lot of papers out</p> <p>2 there.</p> <p>3 Q. Okay.</p> <p>4 A. And I don't know what that</p> <p>5 sentence is referring to.</p> <p>6 Q. Okay. Then it goes on to say,</p> <p>7 "There was heterogeneity in the analysis for</p> <p>8 non-perineal applications of talc. There was</p> <p>9 no heterogeneity for any other outcome</p> <p>10 measures in either the meta-analysis for all</p> <p>11 available studies or subgroup analysis."</p> <p>12 Do you see that?</p> <p>13 A. I do see that.</p> <p>14 Q. Okay. Do you agree with that?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I would just need</p> <p>17 to see the table where it says that.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Well, haven't you seen it</p> <p>20 before?</p> <p>21 A. I have. I just haven't</p> <p>22 memorized it.</p> <p>23 Q. Okay. Well, if you go to</p> <p>24 Table 2, it talks about the type of cancers.</p> <p>25 Serous invasive has a 1.25 with a confidence</p>	<p style="text-align: right;">Page 425</p> <p>1 just asked --</p> <p>2 A. Well, I need to qualify this</p> <p>3 because Penninkilampi left out the -- left</p> <p>4 out Gates, and in Gates there was no</p> <p>5 association between serous.</p> <p>6 Q. I just asked you if you saw it.</p> <p>7 I'm going to ask you a follow-up question.</p> <p>8 Okay?</p> <p>9 Did you see it?</p> <p>10 Did I read it correctly?</p> <p>11 A. You read it correctly.</p> <p>12 Q. I assume you disagree with it.</p> <p>13 MS. MILLER: Objection.</p> <p>14 MR. LOCKE: Objection.</p> <p>15 THE WITNESS: I neither</p> <p>16 disagree -- I'm not disagreeing with</p> <p>17 it. It's just the -- what I do have</p> <p>18 an issue with is the methodology, and</p> <p>19 the methodology in this -- in this</p> <p>20 meta-analysis did not include the</p> <p>21 Gates study. And the Gates study is</p> <p>22 one that was a follow-up to Gertig</p> <p>23 using the same cohort, and that</p> <p>24 association was not in the Gates study</p> <p>25 when found in Gertig with bigger</p>

107 (Pages 422 to 425)

Christian Merlo, M.D., MPH

Page 426	Page 428
<p>1 numbers.</p> <p>2 So I'm not agreeing or</p> <p>3 disagreeing with the statement. I'm</p> <p>4 disagreeing with the methodology that</p> <p>5 led to that statement.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Now, you would agree with me</p> <p>8 that this article was peer-reviewed and</p> <p>9 published, right?</p> <p>10 A. I don't know. I don't know --</p> <p>11 I'm not -- I don't serve on the review</p> <p>12 committee for Epidemiology. I don't know</p> <p>13 what their practices are. I can only speak</p> <p>14 to the journals that I review for and whether</p> <p>15 or not those are peer-reviewed.</p> <p>16 Q. Doctor, isn't it true that</p> <p>17 every meta-analysis done in this case shows</p> <p>18 between a 25 and 40 percent increased --</p> <p>19 statistically significant increased risk of</p> <p>20 ovarian cancer?</p> <p>21 MS. MILLER: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Every published and even</p> <p>24 unpublished meta-analysis shows that risk?</p> <p>25 MR. LOCKE: Objection.</p>	<p>1 just wanted to make sure we were on</p> <p>2 the same page.</p> <p>3 MR. TISI: I don't know why you</p> <p>4 need to confirm that, but, okay, fine,</p> <p>5 I changed the question.</p> <p>6 THE WITNESS: So there are six</p> <p>7 meta-analyses that I reviewed, and</p> <p>8 again, it depends on what we're</p> <p>9 looking at here.</p> <p>10 There's a meta-analysis from</p> <p>11 1995 which -- done by Gross which may</p> <p>12 not have the same quality that</p> <p>13 meta-analyses done later because we</p> <p>14 learned how to do meta-analyses over</p> <p>15 time.</p> <p>16 But also have to remember that</p> <p>17 some of these meta-analyses broke</p> <p>18 things down by type of study, design,</p> <p>19 case-control versus cohort study, and</p> <p>20 even broke it down even further,</p> <p>21 breaking down the case-control studies</p> <p>22 into hospital-based versus</p> <p>23 population-based.</p> <p>24 And it's inappropriate to lump</p> <p>25 them all together, because they're</p>
Page 427	Page 429
<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: We'd have to go</p> <p>3 through each specific one if you want</p> <p>4 me to --</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. Can you think of one that</p> <p>7 doesn't have a statistically significant</p> <p>8 increased risk?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: Again, we'd have</p> <p>11 to go through each -- each one</p> <p>12 individually.</p> <p>13 QUESTIONS BY MR. TISI:</p> <p>14 Q. I'm not asking -- I'm not</p> <p>15 asking you that.</p> <p>16 I'm asking, can you think of</p> <p>17 any meta-analysis that was published or not</p> <p>18 published that shows a nonstatistically</p> <p>19 significant result?</p> <p>20 A. Well --</p> <p>21 MS. MILLER: That's a different</p> <p>22 question.</p> <p>23 MR. TISI: I'm changing the</p> <p>24 question.</p> <p>25 MS. MILLER: Okay. Great. I</p>	<p>1 different study designs.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. But, Doctor, every one of these</p> <p>4 passed peer review, every single one, right?</p> <p>5 MS. MILLER: Objection.</p> <p>6 MR. LOCKE: Objection.</p> <p>7 THE WITNESS: And when you</p> <p>8 break things down further, for</p> <p>9 instance --</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. Well, my --</p> <p>12 A. -- in the Penninkilampi --</p> <p>13 Q. But that wasn't my question,</p> <p>14 Doctor, honestly.</p> <p>15 Every one of these studies</p> <p>16 passed peer review, did they not?</p> <p>17 A. Again, I'm not a -- I'm not a</p> <p>18 reviewer for these -- for these articles.</p> <p>19 Q. I didn't ask you whether you're</p> <p>20 a reviewer. I didn't ask you whether you</p> <p>21 reviewed them. I didn't ask whether you knew</p> <p>22 the process of review. I didn't ask whether</p> <p>23 you reviewed the reviewer comments. I didn't</p> <p>24 ask you anything.</p> <p>25 I asked you: They were all</p>

108 (Pages 426 to 429)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 430</p> <p>1 published in peer-reviewed journals, right?</p> <p>2 MR. LOCKE: Objection.</p> <p>3 THE WITNESS: I don't know.</p> <p>4</p> <p>5 QUESTIONS BY MR. TISI:</p> <p>6 Q. You don't know --</p> <p>7 A. I don't know if these are all</p> <p>8 peer-reviewed journals.</p> <p>9 Q. All right. Let's talk about</p> <p>10 dose response. That's the -- one of the Hill</p> <p>11 aspects, and you spent some time talking</p> <p>12 about that. And you discuss it on page 32 of</p> <p>13 your report.</p> <p>14 Do you see that, sir?</p> <p>15 A. I do see where I talk about</p> <p>16 dose response in my report.</p> <p>17 Q. And you claim on page 45 when</p> <p>18 you're criticizing plaintiffs' experts that</p> <p>19 plaintiffs' experts claim there was dose</p> <p>20 response when none exists, right?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. It's on page 45.</p> <p>24 A. I thought we were on page 32.</p> <p>25 Q. I said, you talk about your</p>	<p style="text-align: right;">Page 432</p> <p>1 literature out there and based on the</p> <p>2 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12,</p> <p>3 13, 14, 15, 16, 17 articles that may</p> <p>4 have -- sorry -- yeah, about that. I</p> <p>5 mean, I haven't tallied them up, but a</p> <p>6 bunch have attempted to look at dose</p> <p>7 response, and that dose response is</p> <p>8 just not there.</p> <p>9 QUESTIONS BY MR. TISI:</p> <p>10 Q. First of all, is dose response</p> <p>11 required for Bradford Hill?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: Again, if we --</p> <p>14 if we go back to Bradford Hill,</p> <p>15 Bradford Hill has considerations, and</p> <p>16 those nine considerations oftentimes</p> <p>17 run into each other.</p> <p>18 Does one or another outweigh</p> <p>19 the other? They're usually used in</p> <p>20 combination.</p> <p>21 QUESTIONS BY MR. TISI:</p> <p>22 Q. Okay.</p> <p>23 A. Is one of them required and an</p> <p>24 absolute? They're considerations that in --</p> <p>25 used in combination can help provide</p>
<p style="text-align: right;">Page 431</p> <p>1 opinions on lack of dose response, and you</p> <p>2 criticize plaintiffs' experts who claim there</p> <p>3 is dose response when none exist.</p> <p>4 A. So on page 32, they're not my</p> <p>5 opinions; that's what's found in the medical</p> <p>6 literature.</p> <p>7 Q. I got it. I hear you, Doctor.</p> <p>8 I'm saying your two parts of</p> <p>9 your discussion, you point out dose response</p> <p>10 on page 32, and that's your interpretation of</p> <p>11 the studies, and your criticisms of the</p> <p>12 plaintiffs' experts appear on page 45.</p> <p>13 MS. MILLER: Objection.</p> <p>14 THE WITNESS: On page 45, I</p> <p>15 talk about where there is no dose</p> <p>16 response, and that would be my</p> <p>17 opinion.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Right. And that plaintiffs are</p> <p>20 just flat out wrong, plaintiffs' experts?</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: I didn't say --</p> <p>23 I'm not saying plain out, flat out</p> <p>24 wrong. What I'm saying is, my</p> <p>25 opinion, based on the medical</p>	<p style="text-align: right;">Page 433</p> <p>1 information on the causal pathway.</p> <p>2 Q. And it is often true with</p> <p>3 exposures as opposed to drugs that it is</p> <p>4 difficult to measure exposure, true?</p> <p>5 We talked about smoking. We</p> <p>6 talked about asbestos. We've talked about</p> <p>7 pollution. We've talked about benzene.</p> <p>8 We've talked about all different kinds of</p> <p>9 exposure.</p> <p>10 It is often difficult to know</p> <p>11 exactly how much a person gets, true?</p> <p>12 MS. MILLER: Objection.</p> <p>13 THE WITNESS: It depends. I</p> <p>14 mean, that's a very general statement.</p> <p>15 I think if we're -- if you have an</p> <p>16 accurate way of measuring something,</p> <p>17 then it's easier. If you don't,</p> <p>18 then --</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Let's take cigarettes.</p> <p>21 A. -- it's more difficult.</p> <p>22 Q. Let's take cigarettes. We use</p> <p>23 pack years, right?</p> <p>24 A. Cigarettes? Pack years would</p> <p>25 be one estimate of the frequency and</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 434</p> <p>1 duration --</p> <p>2 Q. But you don't know how much --</p> <p>3 A. -- of exposure.</p> <p>4 Q. You don't know how much a</p> <p>5 person actually gets, how much they actually</p> <p>6 take into their lungs, whether they complete</p> <p>7 the whole cigarette, whether they go halfway</p> <p>8 and then put it out, whether they just puff</p> <p>9 on it. You don't really know how much they</p> <p>10 actually get, right?</p> <p>11 MS. MILLER: Objection.</p> <p>12 MR. LOCKE: Objection.</p> <p>13 THE WITNESS: Actually, I</p> <p>14 haven't reviewed the literature on</p> <p>15 this, and there may be studies out</p> <p>16 there that I'm just not aware of. And</p> <p>17 there may be studies that have looked</p> <p>18 at how much deposition goes into the</p> <p>19 lungs.</p> <p>20 We have studies looking at</p> <p>21 inhalational antibiotics, and we've</p> <p>22 studied actually how much gets into</p> <p>23 the lungs. I'd have to read</p> <p>24 literature on --</p> <p>25</p>	<p style="text-align: right;">Page 436</p> <p>1 Is it difficult to measure dose</p> <p>2 with exposures like this that are not drugs,</p> <p>3 for example?</p> <p>4 MS. MILLER: Objection.</p> <p>5 THE WITNESS: And I'll say it</p> <p>6 depends. If there is a reliable</p> <p>7 measure of -- if there's a reliable</p> <p>8 method of measuring something --</p> <p>9 because we're talking in generalities.</p> <p>10 If there's a reliable measure, then</p> <p>11 it's easier.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. What's the best way to measure</p> <p>14 talc exposure?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: Measuring talc</p> <p>17 exposure is -- would be very difficult</p> <p>18 to measure because of many, many</p> <p>19 factors.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. Okay. And have you seen where</p> <p>22 articles attempted to figure out a way to do</p> <p>23 that?</p> <p>24 MS. MILLER: Objection.</p> <p>25 THE WITNESS: What kind of</p>
<p style="text-align: right;">Page 435</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Well, those would be clinical</p> <p>3 trials, would they not be? Because you could</p> <p>4 measure that because you're in a controlled</p> <p>5 environment, right?</p> <p>6 A. I'm not sure what you're</p> <p>7 asking.</p> <p>8 Q. What I'm saying is, when you're</p> <p>9 doing an occupational exposure like this, it</p> <p>10 is oftentimes difficult to measure dose --</p> <p>11 MS. MILLER: Objection.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. -- as a general matter?</p> <p>14 MS. MILLER: Objection.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. I mean, I think it's a point</p> <p>17 Dr. Diette made. We sat with Dr. Diette last</p> <p>18 week. He said it's very difficult to measure</p> <p>19 dose.</p> <p>20 MS. MILLER: Objection.</p> <p>21 MR. LOCKE: Objection.</p> <p>22 THE WITNESS: Can you ask me</p> <p>23 that question again?</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. Yes.</p>	<p style="text-align: right;">Page 437</p> <p>1 articles are you referring to?</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. The epidemiology studies, never</p> <p>4 versus ever, breaking it down by weeks, days,</p> <p>5 months, years, et cetera.</p> <p>6 Have you seen those kinds of --</p> <p>7 those kinds of attempts?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: So there are --</p> <p>10 there have been articles that have</p> <p>11 attempted to look at frequency of</p> <p>12 duration and those sorts of things,</p> <p>13 but I think we need to step back a</p> <p>14 little bit because what I'm talking</p> <p>15 about is it's -- it's not a</p> <p>16 medication. There are no pharmacy</p> <p>17 records. There's no dosing. I have</p> <p>18 no idea -- and I don't think anyone</p> <p>19 can tell what -- how much comes out if</p> <p>20 someone's pouring talc on a sanitary</p> <p>21 napkin or underwear or placing talc in</p> <p>22 the perineal area. There's no way to</p> <p>23 know. And there's no article in the</p> <p>24 medical literature that looks at that</p> <p>25 as a measure of exposure.</p>

110 (Pages 434 to 437)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 438</p> <p>1 And that's actually more</p> <p>2 important than frequency and duration</p> <p>3 because we have no idea what even goes</p> <p>4 into that frequency and duration.</p> <p>5 (Merlo Exhibit 30 marked for</p> <p>6 identification.)</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. I'm going to show you what I</p> <p>9 have marked as Exhibit Number 30, which is an</p> <p>10 meta-analysis by Taher. It's not been</p> <p>11 published yet, but it is the draft that we</p> <p>12 have that's been commissioned by Health</p> <p>13 Canada.</p> <p>14 You've seen this before, right?</p> <p>15 A. I've seen Taher. I'm not aware</p> <p>16 that it's commissioned by Health Canada.</p> <p>17 Q. I'll represent to you that it</p> <p>18 is.</p> <p>19 When did you see this study for</p> <p>20 the first time?</p> <p>21 A. I don't recall. Sometime after</p> <p>22 December.</p> <p>23 Q. So if you look at -- if you</p> <p>24 look at the conclusion on the one that says</p> <p>25 page 49 on the bottom, P2.00344.9, it says,</p>	<p style="text-align: right;">Page 440</p> <p>1 off the record for this.</p> <p>2 MR. TISI: Given the way your</p> <p>3 experts have filed things with Health</p> <p>4 Canada, with Dr. Nicholson, not</p> <p>5 identifying who she was when she was</p> <p>6 writing for the Cosmetic Association</p> <p>7 of Canada, I don't think you get to</p> <p>8 talk.</p> <p>9 MS. SHARKO: I think your</p> <p>10 comments are totally off base. You</p> <p>11 asked me why we laughed.</p> <p>12 MR. TISI: It's not even</p> <p>13 appropriate to laugh. Even if you</p> <p>14 thought it was funny, it's not</p> <p>15 appropriate.</p> <p>16 QUESTIONS BY MR. TISI:</p> <p>17 Q. Doctor --</p> <p>18 MS. SHARKO: Well, then don't</p> <p>19 make the obnoxious comments.</p> <p>20 MR. TISI: You don't think</p> <p>21 laughing is obnoxious?</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. On page 26, the summary of</p> <p>24 evidence on biologic gradient exposure</p> <p>25 response.</p>
<p style="text-align: right;">Page 439</p> <p>1 source of funding. "This work was supported</p> <p>2 by Health Canada."</p> <p>3 Do you see that?</p> <p>4 A. I do. "This work was supported</p> <p>5 by Health Canada."</p> <p>6 Q. Do you think Health Canada is</p> <p>7 involved with this litigation?</p> <p>8 MR. LOCKE: Objection.</p> <p>9 THE WITNESS: Again, I told you</p> <p>10 I don't know anything about Health</p> <p>11 Canada.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Do you think that this --</p> <p>14 MR. TISI: You want to talk</p> <p>15 about inappropriate, that was totally</p> <p>16 inappropriate, that laughter.</p> <p>17 MS. SHARKO: Given this --</p> <p>18 given the way your experts are having</p> <p>19 this big ex parte communication with</p> <p>20 Health Canada, I don't think so,</p> <p>21 Mr. Tisi.</p> <p>22 MR. TISI: Given the way --</p> <p>23 given the way -- given the way -- wait</p> <p>24 a second.</p> <p>25 MS. PARFITT: Chris, let's go</p>	<p style="text-align: right;">Page 441</p> <p>1 A. 26?</p> <p>2 Q. There's a chart.</p> <p>3 A. I see it.</p> <p>4 Q. Okay? It discusses -- it</p> <p>5 summarizes the evidence on biologic gradient.</p> <p>6 It says, "About half of the epidemiologic</p> <p>7 studies assessed only one level of talc</p> <p>8 exposure, ever versus never usage."</p> <p>9 Is that correct?</p> <p>10 MR. LOCKE: Objection.</p> <p>11 MS. MILLER: Objection.</p> <p>12 Are you asking --</p> <p>13 MR. TISI: I'm asking what I'm</p> <p>14 asking.</p> <p>15 MS. MILLER: -- whether you</p> <p>16 read it correctly?</p> <p>17 MR. TISI: No. I'm asking is</p> <p>18 that correct.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. "About half of the epidemiology</p> <p>21 studies assessed only one level of talc</p> <p>22 usage, ever versus never."</p> <p>23 MR. LOCKE: Objection.</p> <p>24 THE WITNESS: You know, I would</p> <p>25 have -- I don't have these things</p>

111 (Pages 438 to 441)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 442</p> <p>1 memorized. I'm going to have to go 2 back to each individual article and 3 look to see if it's about half. 4 That's not something that I have 5 memorized. 6 I know that I did look into the 7 different exposure categories or the 8 different levels of exposure in each 9 study, but I didn't lump those into 10 that kind of broad category. 11 QUESTIONS BY MR. TISI: 12 Q. The next one says, "Of the 12 13 studies reporting a positive association, six 14 studies found a significant exposure response 15 trend, particularly with medium and high 16 frequency usage groups. Regarding duration 17 of use, exposure to talc, several studies 18 reported the greatest risk in 20-plus years 19 of exposure group followed by 10 to 20 years 20 group, then less than 10 years group." 21 Do you see that? 22 A. I do see that statement. 23 Q. Now, Bradford Hill doesn't 24 require proof of dose response. It just says 25 if there is evidence of it, that's supportive</p>	<p style="text-align: right;">Page 444</p> <p>1 a biologic gradient, then we should 2 look for it. 3 QUESTIONS BY MR. TISI: 4 Q. Right. 5 And should look for evidence of 6 it? 7 A. Look for such evidence. 8 Q. Right. 9 And it goes -- down at the 10 bottom it says, "Often the difficulty is to 11 secure some satisfactory quantitative measure 12 of environment which will permit us to 13 explore dose response, but we should 14 invariably seek it." 15 Do you agree with that? 16 MS. MILLER: Objection. 17 THE WITNESS: Can you ask me 18 that again? I'm sorry. 19 QUESTIONS BY MR. TISI: 20 Q. Yes. 21 It says, "Often the difficulty 22 in to secure some satisfactory quantitative 23 measure of environment which would permit us 24 to explore this dose response, but we should 25 invariably seek it."</p>
<p style="text-align: right;">Page 443</p> <p>1 of causation, correct? 2 MR. LOCKE: Objection. 3 THE WITNESS: Well, I'm going 4 to have to -- 5 QUESTIONS BY MR. TISI: 6 Q. Let's get it. 7 A. -- refer back to Bradford Hill 8 and see what he says. 9 Q. Let's see what he says. 10 Exhibit Number 14. 11 It's on page 10. 12 A. Okay. 13 Q. It says, "If" -- "Fifthly, if 14 the association is one which can reveal a 15 biologic gradient or a dose-response curve, 16 then we should look most carefully for such 17 evidence." 18 Do you see that? 19 A. I do see that. 20 Q. It doesn't say statistically 21 significant evidence, it doesn't say studies 22 which demonstrate it, does it? 23 MR. LOCKE: Objection. 24 THE WITNESS: It says that if 25 the association is one that can reveal</p>	<p style="text-align: right;">Page 445</p> <p>1 A. That's correct. 2 Q. All right. And so in trying to 3 seek the evidence, these authors, not 4 involved in litigation, found that there was 5 at least evidence of a dose response, 6 correct? 7 MR. LOCKE: Objection. 8 THE WITNESS: I'm going to have 9 to turn back to that page again and 10 look at it because I don't know the 11 exact words. 12 What page is that on again? 13 26? 14 QUESTIONS BY MR. TISI: 15 Q. Yes. And I'll read it again, 16 Doctor. 17 "Of the 12 studies reporting a 18 positive association, six studies found 19 significant exposure response trends, 20 particularly with medium and high frequency 21 usage groups. Regarding duration of use, 22 exposure to talc, several studies reported 23 the greatest risk in the 20-plus years of 24 exposure group, followed by 10 to 20, then 25 less than 10 years."</p>

Christian Merlo, M.D., MPH

Page 446	Page 448
<p>1 A. So...</p> <p>2 MR. LOCKE: Is there a</p> <p>3 question?</p> <p>4 MR. TISI: Yes. That's the</p> <p>5 section I was referring to.</p> <p>6 QUESTIONS BY MR. TISI:</p> <p>7 Q. Isn't that what they found?</p> <p>8 A. That's what they say.</p> <p>9 (Merlo Exhibit 46 marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay. Let me show you Exhibit</p> <p>13 Number 46, which is a compilation exhibit</p> <p>14 that I pulled together, and I tabbed it for</p> <p>15 you with the actual articles. And you can</p> <p>16 check my quotations from it.</p> <p>17 MS. MILLER: I'm going to</p> <p>18 object to this exhibit, of course.</p> <p>19 MR. TISI: Of course you are.</p> <p>20 MS. MILLER: Because you once</p> <p>21 again just pulled random sentences out</p> <p>22 of studies --</p> <p>23 MR. TISI: Okay.</p> <p>24 MS. MILLER: -- that do not</p> <p>25 account for the entire body of</p>	<p>1 genital talc use and ovarian cancer, which</p> <p>2 appears to be limited to serous carcinoma</p> <p>3 with suggestion of dose response."</p> <p>4 Is that --</p> <p>5 MS. MILLER: So you've got the</p> <p>6 ellipses leaving out the "which</p> <p>7 appears to be limited to serous</p> <p>8 carcinoma"?</p> <p>9 MR. TISI: I'm reading it from</p> <p>10 the study, Doctor.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Am I reading that correctly, if</p> <p>13 you look at it?</p> <p>14 MR. LOCKE: Objection. Asked</p> <p>15 and answered.</p> <p>16 THE WITNESS: You're reading</p> <p>17 the abstract.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. Yes. Is that correct.</p> <p>20 I'm just asking you, Doctor,</p> <p>21 whether it says that.</p> <p>22 A. And I said that's what it says</p> <p>23 in the abstract, and I'm looking for where</p> <p>24 that is actually represented in the -- in the</p> <p>25 article.</p>
Page 447	Page 449
<p>1 statements within the studies.</p> <p>2 MR. TISI: Okay.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Now, Doctor, if you look, I</p> <p>5 have the Berge studies we talked about</p> <p>6 before. And you saw the statement, "The</p> <p>7 meta-analysis results in a weak but</p> <p>8 statistically significant association between</p> <p>9 genital use of talc and ovarian cancer which</p> <p>10 appears to be limited to serous with a</p> <p>11 suggestion of dose response."</p> <p>12 Is that correct?</p> <p>13 MR. LOCKE: Objection.</p> <p>14 QUESTIONS BY MR. TISI:</p> <p>15 Q. Is that there in? Can you</p> <p>16 confirm that that's there?</p> <p>17 MS. MILLER: You just said --</p> <p>18 MR. LOCKE: Objection.</p> <p>19 MS. MILLER: That was so fast.</p> <p>20 THE WITNESS: Confirm where</p> <p>21 what is where?</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. Number one says, "The</p> <p>24 meta-analysis resulted in a weak but</p> <p>25 statistically significant association between</p>	<p>1 Q. And in number 2 it says -- on</p> <p>2 the Schildkraut study it has a quote, and</p> <p>3 let's turn to the Schildkraut study. And</p> <p>4 that's number 2. And if you go to page --</p> <p>5 A. But if I could just say,</p> <p>6 because I did find this Table 3 right now,</p> <p>7 looks at duration and frequency.</p> <p>8 Q. Uh-huh.</p> <p>9 A. And the number of risk</p> <p>10 estimates are 12 and the relative risk 1.16,</p> <p>11 with a 95 percent confidence interval, 1.07</p> <p>12 to 1.26. This is just dichotomized duration,</p> <p>13 ten years. This isn't -- that's not a dose</p> <p>14 response. That's yes or no.</p> <p>15 Q. Okay.</p> <p>16 A. Less than ten years or more</p> <p>17 than ten years.</p> <p>18 Q. Okay. Now --</p> <p>19 A. Frequency, one time a week.</p> <p>20 That's not -- that's not a frequency.</p> <p>21 That's -- that's a yes/no, and that's a</p> <p>22 dichotomized -- so that's not a dose</p> <p>23 response.</p> <p>24 Q. Okay. Doctor, in the</p> <p>25 Schildkraut study on number 2, does the</p>

113 (Pages 446 to 449)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 450</p> <p>1 Schildkraut author say on page -- and then if 2 you look at number 2, which is the second 3 article attached on page 1416, the second -- 4 left-hand side, second to last paragraph, 5 second sentence, it says, "The dose response 6 observed for duration of genital powder use 7 provides further evidence of the relationship 8 between genital powder and overall EOC risk." 9 Do you see that? 10 MR. LOCKE: Objection. 11 QUESTIONS BY MR. TISI: 12 Q. I highlighted it for you to 13 make it easy. 14 A. That's what is said in the -- 15 in the paper; however, when you look at 16 Table 2, duration of use, again, it's 17 dichotomized into less than 20 years or 18 greater than 20 years. So there's no full -- 19 never use and genital use. 20 And then it's looked at 21 lifetime body powder applications. Again, 22 dichotomized in above median, 3,600, or 23 below -- or above 3,600. 24 That's not a dose response. A 25 dose response is multiple categories. This</p>	<p style="text-align: right;">Page 452</p> <p>1 dose response? 2 Do you see that? 3 MR. LOCKE: Objection. 4 QUESTIONS BY MR. TISI: 5 Q. Does it not say that, Doctor? 6 Do you see where I'm at, 7 Doctor? 8 A. I do. 9 Q. Okay. Does in not say that? 10 A. It says, "An odds ratio of 1.49 11 was associated with more" -- and I'm sorry, I 12 had to skip a couple pages -- "than 20 talc 13 years, greater than 7,200 applications" -- 14 Q. And -- 15 A. -- "in a dose response." 16 Q. And if you go to page -- 17 A. However, I would like to just 18 look at -- 19 Q. Your lawyer can ask you 20 questions. I asked whether that's in the 21 published article. 22 The next is on page 345, in 23 summary. 24 Do you see that? 25 It says, "Overall, there's an</p>
<p style="text-align: right;">Page 451</p> <p>1 is a dichotomy. This is a yes or no. Is it 2 more or less. That's not a dose response. 3 Q. Okay. Doctor, that's what the 4 authors say that's in the published 5 peer-reviewed literature, correct? 6 MR. LOCKE: Objection. 7 MS. MILLER: Objection. 8 THE WITNESS: I said that 9 that's what it said, but that's not 10 what dose -- 11 QUESTIONS BY MR. TISI: 12 Q. Okay. So why are you going any 13 further than what I asked you? 14 MR. LOCKE: Objection. 15 THE WITNESS: Because that's 16 not what a dose response represents. 17 QUESTIONS BY MR. TISI: 18 Q. All right. Let's go to the 19 next one. Let's go to the Cramer study, 20 which is number 3 and 4. There's two 21 statements here. One is on page 335, and 22 I've highlighted it. 23 Does it say an odds ratio of 24 1.49 was associated with more than 20 talc 25 years, greater than 7,200 applications, in a</p>	<p style="text-align: right;">Page 453</p> <p>1 association between genital talc use and EOC 2 in a significant trend with increasing talc 3 years' use." 4 MR. LOCKE: Is there a 5 question? 6 MR. TISI: Yes. I said, is 7 that correct? 8 MS. MILLER: Is what correct? 9 MR. LOCKE: Objection. 10 QUESTIONS BY MR. TISI: 11 Q. I said do you see it. On 12 page 345, number 1 in the Cramer study, the 13 authors report in the peer-review literature: 14 "Overall, there is an association between 15 genital talc use and epithelial ovarian 16 cancer in a significant trend with increasing 17 talc years' of use." 18 Did I read that right? 19 A. I see that written there. 20 Q. And does it appear in the 21 peer-reviewed literature? 22 MS. MILLER: Objection. 23 THE WITNESS: Again, this is -- 24 it's in the literature. 25</p>

114 (Pages 450 to 453)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 454</p> <p>1 QUESTIONS BY MR. TISI: 2 Q. Okay. 3 A. I can't comment on whether it 4 was peer-reviewed or not. 5 Q. Okay. And the next study, 6 which is the Terry study -- you've seen that 7 study before as well, Doctor? That's 8 number 5? 9 A. I have. 10 Q. Okay. All right. Do you see 11 where -- the statement where it says -- I 12 highlighted it for you. "The association 13 between genital powder exposure and ovarian 14 cancer may not be linear, and a modest 15 exposure may be sufficient to increase the 16 cancer risk." 17 Do you see that? 18 A. I do see that. 19 Q. Okay. Next one is Wu. That's 20 the one where I think you agree there was 21 evidence of dose response, correct? 22 A. Well, the statement in the 23 Terry where it just says, "Alternatively, the 24 associate" -- that's not saying that there's 25 a dose response. That's just stating</p>	<p style="text-align: right;">Page 456</p> <p>1 "However, only about half the studies 2 examined exposure response relationships, and 3 the evidence for this is less consistent. 4 Our study adds to the small group of studies 5 that have investigated a combination of 6 frequency and duration of use of ovarian 7 cancer -- on ovarian cancer." 8 A. So I think -- I think in my 9 report I actually said that Wu, there's a 10 suggestion of a dose response, as well as 11 Cramer 2016, there is a suggestion of dose 12 response. 13 But all the cutoffs were not 14 statistically significant, so, you know -- 15 Q. But, of course -- but, of 16 course, we just agreed that Bradford Hill 17 doesn't require a statistically significant 18 result on dose response. Just says it's good 19 if you have evidence of it. 20 MS. MILLER: Objection. 21 MR. LOCKE: Objection. 22 THE WITNESS: I didn't agree to 23 that. I think that I have to take 24 what this table tells me, and if there 25 is evidence of a dose response based</p>
<p style="text-align: right;">Page 455</p> <p>1 something. 2 Q. Okay. 3 A. It says nothing about dose 4 response. 5 Q. Next one is Wu, number 5. I'm 6 sorry, number 6. 7 A. Number 6. 8 Q. Okay. In the abstract, does it 9 not say, "Risk of ovarian cancer increased 10 significantly with increasing frequency and 11 duration of talc use"? 12 A. So in Wu -- just trying to flip 13 through these. 14 Where'd you read that? 15 Q. In the abstract. It's 16 highlighted for you, Doctor. 17 A. There's a lot going on here 18 really quickly, so I'm just trying my hardest 19 to read everything. 20 So in the abstract it says, 21 "Risk of ovarian cancer increased 22 significantly with increasing frequency and 23 duration of talc use." 24 Q. And does it also say -- and I 25 highlighted it for you as well in the back --</p>	<p style="text-align: right;">Page 457</p> <p>1 on what the numbers look like and is 2 there a consistent increase in risk 3 with increasing duration and 4 frequency, and those numbers are 5 statistically significant, then that 6 would suggest a dose response. 7 However, if we look at the risk 8 estimates in Wu here, looking at 9 Table 2, looking at total number of 10 times, yeah, there is a -- there is a 11 suggestion that there is an increase 12 in risk estimate with increasing 13 number of talc uses, but those numbers 14 are not statistically significant. So 15 they could all be the same or be 16 solely due to chance. 17 MR. TISI: I'm going to take -- 18 THE WITNESS: So it depends. 19 MR. TISI: Okay. I want to 20 take a break. 21 VIDEOGRAPHER: The time is 22 5:22 p.m. We're going off the record. 23 (Off the record at 5:22 p.m.) 24 VIDEOGRAPHER: The time is 25 5:36 p.m. We're back on the record.</p>

115 (Pages 454 to 457)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 458</p> <p>1 QUESTIONS BY MR. TISI:</p> <p>2 Q. Doctor, can you go back to</p> <p>3 Exhibit 32, which was the -- Chapter 2 out of</p> <p>4 the Rothman textbook.</p> <p>5 A. I have it here.</p> <p>6 Q. If you can go to the section on</p> <p>7 biologic gradient.</p> <p>8 MS. MILLER: Can you point us</p> <p>9 to a page?</p> <p>10 MR. TISI: Yeah. It's 28.</p> <p>11 THE WITNESS: 28.</p> <p>12 MS. MILLER: Like where it says</p> <p>13 out of 30?</p> <p>14 MR. TISI: You know, I don't</p> <p>15 have my copy right there. I'm just</p> <p>16 using the book.</p> <p>17 MS. MILLER: Sorry. There's</p> <p>18 like different page numbers.</p> <p>19 MR. TISI: Yeah, if you just</p> <p>20 give me -- it's the one that -- maybe</p> <p>21 I will look at yours. Thank you.</p> <p>22 MS. MILLER: Sure.</p> <p>23 QUESTIONS BY MR. TISI:</p> <p>24 Q. It's page -- it's page 27 out</p> <p>25 of 30.</p>	<p style="text-align: right;">Page 460</p> <p>1 curve. But that -- but that's just</p> <p>2 describing the curve.</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. The last sentence of this says,</p> <p>5 "The issues imply that a -- existence of a</p> <p>6 monotonic association is neither necessary</p> <p>7 nor sufficient for causal relation."</p> <p>8 Is that true or not true?</p> <p>9 A. And I would just have to look</p> <p>10 up to see what monotonic is being defined as.</p> <p>11 Q. So you don't have any</p> <p>12 understanding what the word "monotonic"</p> <p>13 means?</p> <p>14 MS. MILLER: Objection.</p> <p>15 THE WITNESS: Well, I have an</p> <p>16 understanding, but I need to know what</p> <p>17 monotonic is being referred to as</p> <p>18 here.</p> <p>19 QUESTIONS BY MR. TISI:</p> <p>20 Q. Well, what do you -- how do you</p> <p>21 define monotonic?</p> <p>22 MS. MILLER: Objection.</p> <p>23 THE WITNESS: Usually monotonic</p> <p>24 means that there is an increasing risk</p> <p>25 with increasing dose, or a decreasing</p>
<p style="text-align: right;">Page 459</p> <p>1 A. I see it.</p> <p>2 Q. Okay. Do you agree that not</p> <p>3 all bio -- all dose-response relationships</p> <p>4 are linear?</p> <p>5 MS. MILLER: Objection.</p> <p>6 THE WITNESS: There may be</p> <p>7 dose-response relationships that could</p> <p>8 be linear, there may be dose-response</p> <p>9 relationships that may be exponential,</p> <p>10 but in general, a dose response has an</p> <p>11 increasing risk with increasing dose.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. Right.</p> <p>14 But they could be like U-shaped</p> <p>15 curves; they can be J-shaped curves; they</p> <p>16 could be monotonic associations; they could</p> <p>17 be all kinds of associations, right?</p> <p>18 MS. MILLER: Objection.</p> <p>19 THE WITNESS: So if we're</p> <p>20 talking about curves, a curve can look</p> <p>21 like anything. It can be a straight</p> <p>22 line. It can be something that -- J</p> <p>23 goes like a J shape, like you're</p> <p>24 saying. There could be a convex</p> <p>25 curve. There could be a concave</p>	<p style="text-align: right;">Page 461</p> <p>1 risk with decreasing dose.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Okay. Let's just use your</p> <p>4 definition.</p> <p>5 Is the monotonic association</p> <p>6 either necessary or sufficient for causal</p> <p>7 relationship?</p> <p>8 A. Can you ask that again?</p> <p>9 Q. Yeah.</p> <p>10 I'm referring to the sentence</p> <p>11 that -- and Dr. Rothman says, "These issues</p> <p>12 imply that the existence of a monotonic</p> <p>13 association is neither necessary nor</p> <p>14 sufficient for causal relation."</p> <p>15 Is that true or not true using</p> <p>16 your definition of monotonic?</p> <p>17 A. Well, if we go back to the</p> <p>18 original Bradford Hill considerations,</p> <p>19 biologic gradient is only one of the</p> <p>20 considerations. And if we're talking about a</p> <p>21 causal relationship, we need to consider the</p> <p>22 other considerations as well.</p> <p>23 Q. But, Doctor, that's not my</p> <p>24 question. Okay?</p> <p>25 So my question is -- I'm</p>

116 (Pages 458 to 461)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 462</p> <p>1 focused now on biologic gradient or dose 2 response. 3 Would you agree with 4 Dr. Rothman that a monotonic association, 5 meaning increasing dose with increasing 6 duration -- with increasing risk, is neither 7 necessary nor sufficient for causal relation? 8 MS. MILLER: Objection. 9 THE WITNESS: And again, I'm 10 going to have to go back to what I 11 just said because I'm not sure what 12 Dr. Rothman is referring to here. 13 Is it just specifically for 14 biologic gradient -- 15 QUESTIONS BY MR. TISI: 16 Q. Yeah. 17 A. -- or is it -- well -- 18 Q. Let's assume that's what he's 19 saying, because I want to know if, on its 20 own, a -- on its own, is it necessary to have 21 a increasing risk with increasing dose -- 22 MS. MILLER: Objection. 23 QUESTIONS BY MR. TISI: 24 Q. -- to show causation? 25 MS. MILLER: Objection.</p>	<p style="text-align: right;">Page 464</p> <p>1 Remember that? 2 MR. LOCKE: Objection. 3 THE WITNESS: We would have to 4 refer back to what -- what I said. 5 QUESTIONS BY MR. TISI: 6 Q. Okay. 7 A. I don't recall specifically my 8 language. 9 Q. Is it necessary to have a 10 dose-response relationship in order to show 11 causation? Is that a required element? 12 A. I think what I said earlier is 13 that of the nine Bradford Hill 14 considerations, none of them are required. 15 Q. Okay. 16 A. They're helpful in making an -- 17 in making -- in putting together an 18 evaluation looking at causality. 19 Q. Is Dr. Rothman's statement here 20 wrong? 21 MS. MILLER: Objection. 22 QUESTIONS BY MR. TISI: 23 Q. Is the existence of a monotonic 24 association -- he says, "The existence of a 25 monotonic association is neither necessary</p>
<p style="text-align: right;">Page 463</p> <p>1 THE WITNESS: Again, I will go 2 back to the Bradford Hill 3 considerations, and that of the nine 4 considerations, none of them or all of 5 them could support causation. 6 QUESTIONS BY MR. TISI: 7 Q. Okay. 8 A. I'm not going to say none of 9 them, but all of them could support 10 causation. 11 Does one factor -- does one 12 factor weigh in more than another factor? 13 Not necessarily. 14 And this sentence can't be 15 taken out of context in the -- from the 16 Bradford Hill considerations. 17 Q. I hear you, Doctor, but I'm 18 going to ask you to listen to my question. 19 Is it necessary to have a dose 20 response to find causation? 21 You said before that it was 22 necessary to have a consistent association, I 23 think a clear association -- that was your 24 testimony before -- to even get to Bradford 25 Hill.</p>	<p style="text-align: right;">Page 465</p> <p>1 nor sufficient for causal relations." 2 Is that wrong? 3 MS. MILLER: Objection. 4 THE WITNESS: I'm going to say 5 it depends. If you have nine other -- 6 or eight other factors that suggest 7 causation and there's -- and a 8 biologic gradient doesn't exist 9 because you haven't tested for it or 10 it's just isn't showing that, you have 11 to consider the other factors. 12 If biologic gradient is the 13 only thing, and we're not seeing 14 strength of association and 15 consistency, then it becomes difficult 16 to rely on that -- just the biologic 17 gradient. So I'm just going to say it 18 depends. 19 QUESTIONS BY MR. TISI: 20 Q. Okay. So if you go to the 21 Penninkilampi study back -- I forget which 22 exhibit it was. But if you can pull that out 23 if you can find it, sir. 24 A. Sure. 25 MR. TISI: Do you know what</p>

117 (Pages 462 to 465)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 466</p> <p>1 exhibit it was?</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. 21, please.</p> <p>4 A. 21. Got it.</p> <p>5 Q. You were critical of that study</p> <p>6 because Penninkilampi included Gertig but not</p> <p>7 Gates.</p> <p>8 Do you recall that?</p> <p>9 MS. MILLER: Objection.</p> <p>10 THE WITNESS: I did make</p> <p>11 reference that Gertig was included in</p> <p>12 this meta-analysis and Gates was not,</p> <p>13 which is a more recent publication</p> <p>14 with greater numbers.</p> <p>15 QUESTIONS BY MR. TISI:</p> <p>16 Q. Which Gates did you mean?</p> <p>17 Which Gates study did you mean should have</p> <p>18 been included that wasn't?</p> <p>19 A. I'll just need to look up the</p> <p>20 specific one in my report. Gates 2010.</p> <p>21 Q. Okay. What was the talc</p> <p>22 exposure metric in Gates 2010?</p> <p>23 A. If I could see the article, I</p> <p>24 could...</p> <p>25 Q. Is it in your report?</p>	<p style="text-align: right;">Page 468</p> <p>1 asked that question.</p> <p>2 QUESTIONS BY MR. TISI:</p> <p>3 Q. Could that have been --</p> <p>4 MR. TISI: Counsel, I'm not</p> <p>5 even done, okay?</p> <p>6 MS. MILLER: It sounded like a</p> <p>7 question.</p> <p>8 MR. TISI: I'm not done.</p> <p>9 MS. MILLER: Apologies.</p> <p>10 QUESTIONS BY MR. TISI:</p> <p>11 Q. In the Gates -- in the Gates</p> <p>12 study, do you know that talc use metric was</p> <p>13 great or equal to one week versus less --</p> <p>14 versus less than one time a week?</p> <p>15 MS. MILLER: Objection.</p> <p>16 THE WITNESS: I'd love to look</p> <p>17 at it.</p> <p>18 QUESTIONS BY MR. TISI:</p> <p>19 Q. I'm happy to show it. I'm</p> <p>20 happy to show it to you. It's my copy, so</p> <p>21 you can't have it. But it's in Table 4, and</p> <p>22 this is Gates 2010.</p> <p>23 A. So Table 4 says, talc use,</p> <p>24 greater than once a week versus less than</p> <p>25 once a week.</p>
<p style="text-align: right;">Page 467</p> <p>1 A. I could point to it.</p> <p>2 Q. Is it in your report?</p> <p>3 A. No, but I know that it was --</p> <p>4 but I would have to see the article because I</p> <p>5 don't specifically remember what the</p> <p>6 actual -- I don't want to be mistaken right</p> <p>7 now.</p> <p>8 Q. Well, Penninkilampi used an</p> <p>9 ever use of talc, correct, as its metric?</p> <p>10 A. I mean, Table 1 in</p> <p>11 Penninkilampi summarizes the different</p> <p>12 outcomes in the methods of talc use.</p> <p>13 Q. Right.</p> <p>14 A. There's any perineal, there's</p> <p>15 non-perineal, there's diaphragm, and there's</p> <p>16 sanitary napkins.</p> <p>17 Q. Well, if you look at</p> <p>18 Penninkilampi under Figure 2 -- on the study</p> <p>19 name. Under Figure 2 it says "any perineal</p> <p>20 talc use."</p> <p>21 Do you see?</p> <p>22 A. I do see that.</p> <p>23 Q. Okay. Do you know what the</p> <p>24 metric was in Gates?</p> <p>25 MS. MILLER: I believe you</p>	<p style="text-align: right;">Page 469</p> <p>1 Q. Right.</p> <p>2 So it's a different metric, is</p> <p>3 it not?</p> <p>4 A. It may or may not be a</p> <p>5 different metric because there is a previous</p> <p>6 publication where the authors felt that this</p> <p>7 was a more reliable measure of exposure of</p> <p>8 ever versus never.</p> <p>9 Q. The point is, Doctor, you were</p> <p>10 critical of Penninkilampi as to why they</p> <p>11 didn't include Gates 2010. And I'm asking</p> <p>12 you: Would that be good reason not to</p> <p>13 include Gates 2010, because it used a</p> <p>14 different metric of exposure?</p> <p>15 MS. MILLER: Objection. Calls</p> <p>16 for speculation.</p> <p>17 THE WITNESS: No, not</p> <p>18 necessarily, because the authors felt</p> <p>19 that this -- that this metric was</p> <p>20 actually a more reliable metric of</p> <p>21 ever versus never.</p> <p>22 QUESTIONS BY MR. TISI:</p> <p>23 Q. Okay. In the Gertig study,</p> <p>24 they use ever versus ever talc use.</p> <p>25 MS. MILLER: Objection. You</p>

118 (Pages 466 to 469)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 470</p> <p>1 said ever versus ever. 2 QUESTIONS BY MR. TISI: 3 Q. They used ever use. 4 Gates -- Gertig used ever 5 versus never, correct? 6 A. Gertig? Again, I don't have 7 these memorized, so I'm going to have to look 8 at it to see what we're referring to. 9 Q. But the big question is you 10 don't -- you can't sit here today and tell me 11 why it is that Penninkilampi did not use 12 Gates 2010, can you? 13 It's not in your report, and 14 you can't tell me today? 15 MS. MILLER: Objection. Asked 16 and answered. 17 THE WITNESS: The description 18 of the -- of the pulling of articles 19 for the meta-analysis is described. 20 The replication of that would have to 21 be performed to answer that question. 22 QUESTIONS BY MR. TISI: 23 Q. And you didn't do that, did 24 you? 25 A. For me to -- for me to perform</p>	<p style="text-align: right;">Page 472</p> <p>1 kinds of stuff. You find time for those. 2 My question to you is: Would 3 you find time do this, to submit your point 4 of view to peer review? 5 MS. MILLER: Objection. 6 THE WITNESS: Again, I'm going 7 to have to answer it the same -- the 8 same way, that if an opportunity arose 9 and it seemed like an interesting 10 investigation -- 11 QUESTIONS BY MR. TISI: 12 Q. Is it an interesting 13 investigation to you, or is this just 14 something you did for this case? 15 MS. MILLER: Objection. 16 THE WITNESS: This has -- this 17 has been a very interesting exercise 18 in evaluating epidemiology. 19 QUESTIONS BY MR. TISI: 20 Q. And so now having been through 21 the process, do you intend to subject your 22 opinions, particularly the ones where you 23 were very strong in your criticism of those 24 who have published and have put themselves 25 out there, subject your opinions to peer</p>
<p style="text-align: right;">Page 471</p> <p>1 my own meta-analysis by myself would be out 2 of the scope of even performing an analysis 3 per -- a meta-analysis correctly. 4 Q. Doctor -- 5 A. I'm going to need a team to do 6 that. 7 Q. Okay. We started our day today 8 talking about publication and, you know, 9 opinions inside and outside litigation and 10 all those questions. 11 Let me ask you this: You spent 12 seven hours with me today. You wrote your 13 report. You've been through this process. 14 Do you intend to publish your 15 views on ovarian cancer and talc? 16 A. I have no idea what I'm going 17 to do in the future. I -- I am a -- I have 18 an active research career in cystic fibrosis 19 and lung transplantation. 20 If the opportunity arose where 21 there was something to publish and seemed 22 interesting, fine, but I can't predict that. 23 Q. Well, you're also pretty busy 24 in litigation. You do four, five cases a 25 year. You do speakers bureaus. You do all</p>	<p style="text-align: right;">Page 473</p> <p>1 review? 2 MR. LOCKE: Objection. 3 THE WITNESS: Well -- 4 QUESTIONS BY MR. TISI: 5 Q. Dr. Siemiatycki has put himself 6 out there and submitted himself -- 7 MS. MILLER: He started 8 answering the question -- 9 QUESTIONS BY MR. TISI: 10 Q. Well, let me ask you this. 11 MS. MILLER: -- and you 12 interrupted him. Can we just end the 13 day with question, answer, question, 14 answer? 15 QUESTIONS BY MR. TISI: 16 Q. Okay. Dr. Siemiatycki 17 published in this, correct? 18 MS. MILLER: Objection. 19 THE WITNESS: I'm going to have 20 to look through what's been published 21 by Dr. Siemiatycki. 22 QUESTIONS BY MR. TISI: 23 Q. Okay. Dr. McTiernan went 24 before Congress and gave her testimony, 25 correct?</p>

119 (Pages 470 to 473)

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 474</p> <p>1 MR. LOCKE: Objection.</p> <p>2 THE WITNESS: Again, I told you</p> <p>3 I didn't know about that.</p> <p>4 QUESTIONS BY MR. TISI:</p> <p>5 Q. Dr. Smith-Bindman said she's</p> <p>6 going to submit her meta-analysis to</p> <p>7 publication.</p> <p>8 Do you remember seeing that?</p> <p>9 A. You'd have to show me where she</p> <p>10 said that.</p> <p>11 Q. Dr. Moorman was a coauthor on</p> <p>12 the Schildkraut study, correct?</p> <p>13 A. I'd have to look back through</p> <p>14 the list of authors to confirm or not</p> <p>15 confirm.</p> <p>16 Q. Some of them wrote Health</p> <p>17 Canada, as counsel pointed out, to express</p> <p>18 their point of views on this in the comment</p> <p>19 period, correct?</p> <p>20 A. I have no idea.</p> <p>21 Q. Do you have any intention, now</p> <p>22 having been through this process, as you sit</p> <p>23 here today, to submit your criticisms and</p> <p>24 your opinions to the criticisms of your</p> <p>25 fellow peers?</p>	<p style="text-align: right;">Page 476</p> <p>1 tell our patients to stop using talcum</p> <p>2 powder, what would you tell them?</p> <p>3 MS. MILLER: Objection.</p> <p>4 THE WITNESS: Again, I -- I'd</p> <p>5 say it depends. If you're talking</p> <p>6 about based on the medical evidence</p> <p>7 out there, there's no evidence to</p> <p>8 suggest that -- and if we're</p> <p>9 specifically talking about risk of</p> <p>10 ovarian cancer --</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Yes.</p> <p>13 A. -- there's no evidence to</p> <p>14 suggest a causal relationship between talcum</p> <p>15 powder and ovarian cancer.</p> <p>16 Q. No evidence whatsoever?</p> <p>17 A. Based on the body of medical</p> <p>18 literature, no, there is not evidence --</p> <p>19 Q. And so you would --</p> <p>20 A. -- but there is a --</p> <p>21 Q. You would tell them --</p> <p>22 MS. MILLER: He's in a middle</p> <p>23 of a sentence.</p> <p>24 THE WITNESS: So what I said is</p> <p>25 it would depend. If we're talking</p>
<p style="text-align: right;">Page 475</p> <p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: Submit where?</p> <p>3 QUESTIONS BY MR. TISI:</p> <p>4 Q. Anywhere. Congress, medical</p> <p>5 meetings, regulatory authorities,</p> <p>6 publications, peer review, your colleagues,</p> <p>7 anywhere.</p> <p>8 MS. MILLER: Objection.</p> <p>9 THE WITNESS: And I'll just</p> <p>10 have to say I have no idea.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. Okay.</p> <p>13 A. There's a possibility that</p> <p>14 something may arise in the future and I may</p> <p>15 take up that opportunity. And I don't know</p> <p>16 today.</p> <p>17 Q. Have you gone -- have you gone</p> <p>18 to your oncology department here -- you have</p> <p>19 an oncology department here at -- or a</p> <p>20 gynecology department here at Hopkins?</p> <p>21 A. We do have a --</p> <p>22 Q. Gynecology?</p> <p>23 A. -- a gynecology department.</p> <p>24 Q. Okay. If a gynecology</p> <p>25 department asked you, do you think we should</p>	<p style="text-align: right;">Page 477</p> <p>1 about the medical literature, that</p> <p>2 would be my response, that -- that</p> <p>3 that causal relationship does not</p> <p>4 exist based on the evidence.</p> <p>5 But if a doctor is asking -- if</p> <p>6 a gynecologist is asking me whether or</p> <p>7 not talcum powder should be used for a</p> <p>8 specific patient, it's going to be</p> <p>9 dependent on that specific patient.</p> <p>10 There might be a wound in there.</p> <p>11 There might be some other reason --</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. I'm not asking that.</p> <p>14 A. Well, that's --</p> <p>15 Q. I'm not asking that. I'm</p> <p>16 asking --</p> <p>17 A. But that's what I'm saying.</p> <p>18 You asked me if I would recommend, and so</p> <p>19 I'll telling you that it depends. It</p> <p>20 depends.</p> <p>21 Q. If a gynecologist came to you</p> <p>22 and said, "Doctor, you're an epidemiologist,</p> <p>23 I have women who are asking me whether or not</p> <p>24 I should -- they hear what's on the radio,</p> <p>25 they hear what's on television. They're</p>

120 (Pages 474 to 477)

Christian Merlo, M.D., MPH

Page 478	Page 480
<p>1 aware of a potential link that's been</p> <p>2 discussed out there. Should I tell my women</p> <p>3 to stop or should I tell them to continue</p> <p>4 using it?" what would you tell them?</p> <p>5 Continue using it?</p> <p>6 MS. MILLER: Objection, vague,</p> <p>7 and objection, asked and answered.</p> <p>8 THE WITNESS: So I would ask</p> <p>9 why, and it would be dependent on the</p> <p>10 answer to why.</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. If they said because there's a</p> <p>13 concern that they might put myself at</p> <p>14 increased risk of ovarian cancer?</p> <p>15 MS. MILLER: Objection. This</p> <p>16 was asked and answered.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. If they said -- if they said</p> <p>19 that was the reason why, what would you</p> <p>20 answer -- would you respond to them?</p> <p>21 A. I would say, based on the body</p> <p>22 of medical evidence, there is no causal</p> <p>23 association between talcum powder and ovarian</p> <p>24 cancer.</p> <p>25 Q. Okay. So you'd tell them, keep</p>	<p>1 MS. MILLER: Of course.</p> <p>2 MR. TISI: Can you find --</p> <p>3 would you pull them over...</p> <p>4 QUESTIONS BY MS. MILLER:</p> <p>5 Q. We're going to be looking at</p> <p>6 page 11.</p> <p>7 MR. TISI: I'm sorry, he just</p> <p>8 started putting them away.</p> <p>9 MS. MILLER: It's</p> <p>10 understandable. I think everybody</p> <p>11 wants to get home for the weekend.</p> <p>12 QUESTIONS BY MS. MILLER:</p> <p>13 Q. I'm looking at the bottom of</p> <p>14 page -- of page 11 in Exhibit 31.</p> <p>15 Do you recall Exhibit 31 was</p> <p>16 shown to you earlier today?</p> <p>17 A. I do.</p> <p>18 Q. And this is a document from the</p> <p>19 National Cancer Institute; is that correct?</p> <p>20 A. That's what it appears to be.</p> <p>21 Q. The title is "Ovarian,</p> <p>22 Fallopian Tube and Primary Peritoneal Cancer</p> <p>23 Prevention," correct?</p> <p>24 A. Correct.</p> <p>25 Q. There's a section on page 11</p>
Page 479	Page 481
<p>1 dusting?</p> <p>2 MS. MILLER: Objection.</p> <p>3 THE WITNESS: I didn't say</p> <p>4 that. I said based on the body of</p> <p>5 medical evidence, there is no</p> <p>6 association, causal association,</p> <p>7 between talcum powder and ovarian</p> <p>8 cancer.</p> <p>9 There may be other reasons that</p> <p>10 that gynecologist would or would not</p> <p>11 recommend using talcum powder.</p> <p>12 MR. TISI: Doctor, I appreciate</p> <p>13 your time today. I have no further</p> <p>14 questions.</p> <p>15 Anything else? Do you have any</p> <p>16 questions?</p> <p>17 MS. MILLER: We're discussing</p> <p>18 it. I just have two questions.</p> <p>19 CROSS-EXAMINATION</p> <p>20 QUESTIONS BY MS. MILLER:</p> <p>21 Q. Can you go back to Exhibit 31?</p> <p>22 A. 31.</p> <p>23 Q. Okay. Can you turn to --</p> <p>24 MR. TISI: Can you wait until I</p> <p>25 get my copy, Counsel?</p>	<p>1 titled "Perineal Talc Exposure."</p> <p>2 Do you see that?</p> <p>3 MR. TISI: It's on page 11? I</p> <p>4 don't see it on page 11.</p> <p>5 MS. MILLER: Page 11 of 17.</p> <p>6 QUESTIONS BY MS. MILLER:</p> <p>7 Q. Do you see that section?</p> <p>8 MR. TISI: No, I don't,</p> <p>9 actually. Can you show me?</p> <p>10 THE WITNESS: I do.</p> <p>11 MR. TISI: I see oophorectomy</p> <p>12 on page 11.</p> <p>13 MS. MILLER: You've got --</p> <p>14 you've got a different version than</p> <p>15 the one you used as an exhibit. It's</p> <p>16 on page 11 of the one you used as an</p> <p>17 exhibit.</p> <p>18 MR. TISI: Okay. I'll have to</p> <p>19 argue this when we're done.</p> <p>20 QUESTIONS BY MS. MILLER:</p> <p>21 Q. Did counsel direct you to this</p> <p>22 section of the exhibit when he was</p> <p>23 questioning you about it?</p> <p>24 MR. TISI: Objection to form.</p> <p>25 THE WITNESS: Not that I</p>

121 (Pages 478 to 481)

Christian Merlo, M.D., MPH

Page 482	Page 484
<p>1 recall.</p> <p>2 QUESTIONS BY MS. MILLER:</p> <p>3 Q. Did you see this section when</p> <p>4 you were asked questions about this document?</p> <p>5 MR. TISI: Objection to form.</p> <p>6 THE WITNESS: Not that I</p> <p>7 recall.</p> <p>8 QUESTIONS BY MS. MILLER:</p> <p>9 Q. Can you read the first sentence</p> <p>10 under Perineal Talc Exposure?</p> <p>11 A. Sure.</p> <p>12 "The weight of evidence does</p> <p>13 not support an association between perineal</p> <p>14 talc exposure and an increased risk of</p> <p>15 ovarian cancer."</p> <p>16 Q. Can you read the second</p> <p>17 sentence?</p> <p>18 A. "Results from case control and</p> <p>19 cohort studies are inconsistent."</p> <p>20 MS. MILLER: I have no further</p> <p>21 questions at this time.</p> <p>22 MR. TISI: May have it, please?</p> <p>23 MS. MILLER: Well, don't take</p> <p>24 his because --</p> <p>25 MR. TISI: Well, okay, can I</p>	<p>1 exposure it has footnotes 43, 44, 45 and 46.</p> <p>2 Do you see that?</p> <p>3 A. Okay.</p> <p>4 Q. Do you see that?</p> <p>5 A. Yeah, I see 42 through 45, yes.</p> <p>6 Q. And if you go to the back of</p> <p>7 the thing where they -- the back of this --</p> <p>8 they only looked at four studies.</p> <p>9 Do you see that?</p> <p>10 A. What are you referring to?</p> <p>11 Q. Well, the footnotes, they look</p> <p>12 at 43, 44, 45 and 46. They have four</p> <p>13 references: Huncharek, Terry, Gertig and</p> <p>14 Houghton.</p> <p>15 One is the Huncharek study</p> <p>16 which in your footnote in your report you</p> <p>17 indicated you agree that there are mistakes</p> <p>18 in those, right?</p> <p>19 MS. MILLER: Objection.</p> <p>20 QUESTIONS BY MR. TISI:</p> <p>21 Q. You looked at the report of</p> <p>22 April Zambelli-Weiner, correct?</p> <p>23 A. I did look at that, yes.</p> <p>24 Q. Okay. And you agree that there</p> <p>25 were mistakes in that?</p>
Page 483	Page 485
<p>1 have -- may I have yours then?</p> <p>2 MS. MILLER: Well, mine is</p> <p>3 marked.</p> <p>4 MR. TISI: Okay. Well, I --</p> <p>5 MS. MILLER: You don't have it?</p> <p>6 MR. TISI: I don't. I have the</p> <p>7 different copy.</p> <p>8 MS. MILLER: If you give it to</p> <p>9 me, I'll show you what page it is.</p> <p>10 REDIRECT EXAMINATION</p> <p>11 QUESTIONS BY MR. TISI:</p> <p>12 Q. All right. So, Doctor, first</p> <p>13 of all, you testified earlier you don't even</p> <p>14 know who these authors are who did this,</p> <p>15 correct?</p> <p>16 MR. LOCKE: Objection.</p> <p>17 QUESTIONS BY MR. TISI:</p> <p>18 Q. Earlier?</p> <p>19 MS. MILLER: Objection.</p> <p>20 THE WITNESS: It looks like</p> <p>21 this is from the National Cancer</p> <p>22 Institute, but I don't know who put</p> <p>23 this all together.</p> <p>24 QUESTIONS BY MR. TISI:</p> <p>25 Q. So now in the perineal talc</p>	<p>1 MS. MILLER: Objection.</p> <p>2 THE WITNESS: The numbers may</p> <p>3 have been off, but the general gist of</p> <p>4 the trend was still the same, meaning</p> <p>5 the numbers didn't affect statistical</p> <p>6 significance, as I recall.</p> <p>7 QUESTIONS BY MR. TISI:</p> <p>8 Q. And this is not -- this</p> <p>9 study -- studies four -- it has four</p> <p>10 references. You have some 30 --</p> <p>11 MS. MILLER: We're out of time.</p> <p>12 QUESTIONS BY MR. TISI:</p> <p>13 Q. You have some 30 references.</p> <p>14 Are you going to tell me that</p> <p>15 they did a full causation analysis that you</p> <p>16 did?</p> <p>17 MS. MILLER: Objection. And</p> <p>18 we're out of time.</p> <p>19 MR. TISI: You're not going to</p> <p>20 let him answer that question?</p> <p>21 MS. SHARKO: He can answer that</p> <p>22 one question.</p> <p>23 MR. TISI: Thank you.</p> <p>24 THE WITNESS: I don't know what</p> <p>25 they did here.</p>

Christian Merlo, M.D., MPH

<p style="text-align: right;">Page 486</p> <p>1 MR. TISI: Thank you very much. 2 I appreciate it. 3 VIDEOGRAPHER: Okay. That's 4 it. 5 MS. MILLER: Thank you. 6 VIDEOGRAPHER: The time is 7 6:01 p.m., April 18, 2019. Going off 8 the record, completing the videotaped 9 deposition. 10 (Deposition concluded at 6:01 p.m.) 11 ----- 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 488</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 487</p> <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomate Reporter, Certified Realtime 5 Reporter and Certified Shorthand Reporter, do 6 hereby certify that prior to the commencement 7 of the examination, Christian Merlo, MD, MPH 8 was duly sworn by me to testify to the truth, 9 the whole truth and nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a verbatim transcript of the 12 testimony as taken stenographically by and 13 before me at the time, place and on the date 14 hereinbefore set forth, to the best of my 15 ability. 16 17 I DO FURTHER CERTIFY that I am 18 neither a relative nor employee nor attorney 19 nor counsel of any of the parties to this 20 action, and that I am neither a relative nor 21 employee of such attorney or counsel, and 22 that I am not financially interested in the 23 action. 24 25 CARRIE A. CAMPBELL, NCRA Registered Diplomate Reporter Certified Realtime Reporter Notary Public Dated: April 19, 2019</p>	<p style="text-align: right;">Page 489</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 4 I, _____, do 5 hereby certify that I have read the foregoing 6 pages and that the same is a correct 7 transcription of the answers given by me to 8 the questions therein propounded, except for 9 the corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet. 12 13 14 15 Christian Merlo, M.D., MPH DATE 16 17 Subscribed and sworn to before me this 18 _____ day of _____, 20 _____. 19 My commission expires: _____ 20 21 Notary Public 22 23 24 25</p>

123 (Pages 486 to 489)

Christian Merlo, M.D., MPH

Page 490		
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Page 491		
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124 (Pages 490 to 491)